April 1, 2019

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

CMS received many submissions in response to our request for comments on Part I of the Advance Notice, published on December 20, 2018 and Part II of the Advance Notice/Draft Call Letter, published on January 30, 2019. Comments were received from professional organizations, Medicare Advantage (MA) and Part D sponsors, advocacy groups, state Medicaid agencies, pharmaceutical manufacturers, pharmacy benefit managers, pharmacies, and concerned citizens. In response to the comments, we made a number of changes in the Rate Announcement and Call Letter that reflect CMS's continued commitment to providing Medicare Advantage Organizations and Part D Plan Sponsors with the flexibility to develop and implement innovative approaches for providing Medicare benefits to enrollees and empowering enrollees. CMS expects the additional flexibility will result in additional and more affordable plan choices for Medicare beneficiaries. CMS is committed to exploring other avenues for simplifying and transforming the MA and Part D programs in order to encourage innovation and expand beneficiary choice, and is looking forward to working with stakeholders to achieve those shared goals.

In accordance with section 1853(b)(1) of the Social Security Act, we are notifying you of the annual capitation rate for each MA payment area for CY 2020 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2020 and supporting data are posted on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The statutory component of the regional benchmarks, qualifying counties, and each county's applicable percentage are also posted on this section of the CMS website.

Attachment I shows the final estimates of the National Per Capita MA Growth Percentage for 2020 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2020. These growth rates were used to calculate the 2020 capitation rates. As discussed in Attachment I, the final estimate of the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 5.79 percent, and the final estimate of the FFS Growth Percentage is 5.58 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the growth percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with

this requirement, FFS data for CY 2017 were posted on the above website with Part II of the Advance Notice.

Attachment II details the key assumptions and financial information behind the growth percentages presented in Attachment I.

Attachment III presents responses to Part C payment related comments on both Parts I and II of the Advance Notice of Methodological Changes for CY 2020 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice).

Attachment IV presents responses to Part D payment related comments on the Advance Notice.

Attachment V shows the final Part D benefit parameters and contains details on how they are updated.

Attachment VI shows the CMS-HCC, ESRD, and RxHCC Risk Adjustment Factors.

Attachment VII presents the final Call Letter.

Key Changes from the Advance Notice:

Growth Percentages: Attachment I provides the final estimates of the National Per Capita MA Growth Percentage and the FFS Growth Percentage and information on deductibles for MSAs.

Calculation of FFS Cost: The Secretary has directed the CMS Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide.

In addition, we are specifying the inclusion of certain fees paid in one CMS Innovation Center model in our adjustment of historical FFS claims experience. We stated in the Advance Notice that care management fees would not be accounted for in the adjustments to historical FFS experience when they were funded from other sources (that is, when they're not funded by Medicare Trust Funds). Specifically, we note that since the care management fees for the Comprehensive Primary Care Plus (CPC+) model are paid out of the Part B Trust Fund, the CPC+ model care management fees will be included in the adjustments to historical FFS claims experience, consistent with the approach described in the Advance Notice.

CMS-HCC Risk Adjustment Model: For 2020 CMS will use the alternative payment condition count (APCC) model for the blended risk score calculation; this model includes additional HCCs for Dementia and Pressure Ulcers as well as variables that take into account the number of conditions a beneficiary may have. Therefore, for 2020 we will calculate risk scores as proposed, but with the alternative payment condition count model described in Part I of the 2020 Advance Notice. Specifically, we will blend 50% of the risk score using the 2017 CMS-HCC model, using diagnoses from RAPS and FFS, summed with 50% of the risk score calculated with the alternative payment condition count model, using diagnoses from encounter data, RAPS inpatient records, and FFS as discussed in Attachment III, Sections G and L. In reviewing the APCC model coefficients, CMS identified two HCC constraints that were inappropriately applied in the non-dual aged segment. Attachment VI contains the risk adjustment factors for the alternative payment condition count model; including the updated factors for the non-dual aged segment.

Proposals Adopted as Issued in the Advance Notice:

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year. Clarifications in the Rate Announcement supersede materials in the Advance Notice and prior Rate Announcements.

Final 2020 Normalization Factors:
2020 Alternative Payment Condition Count Model (APCC): 1.069
2017 CMS-HCC Model: 1.075
CMS-HCC 2019 ESRD dialysis model & 2020 ESRD dialysis model: 1.059

CMS-HCC 2019 ESRD Functioning Graft model & 2020 ESRD Functioning Graft model: 1.084
2020 RxHCC model (14/15 calibration): 1.043

Frailty Adjustment for PACE organizations and FIDE-SNPs: CMS will implement FIDE-SNP frailty factors consistent with the version of the CMS-HCC model being finalized for 2020. Consistent with CMS's proposal to blend risk scores, a blended frailty score for FIDE SNPs will be compared with PACE frailty in the same manner as for 2019 to determine whether that FIDE SNP has a similar average level of frailty as PACE.

MA Benchmark, Quality Bonus Payments and Rebate: We will continue to implement the methodology used to derive the benchmark county rates, how the qualifying bonus counties will be identified, and the applicability of the star rating system.

IME Phase Out: We will continue phasing out indirect medical education amounts from the MA capitation rates.

End Stage Renal Disease (ESRD) State Rates: We will determine the ESRD dialysis rates by state as we specified in the Advance Notice.

Location of Network Areas for Private Fee-for-Service (PFFS) Plans in Plan Year 2021: The list of network areas for plan year 2021 is available on the CMS website at https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html.

MA Employer Group Waiver Plans: We are finalizing the payment methodology as proposed, continuing for 2020 the payment methodology implemented for MA EGWPs finalized in the 2019 Rate Announcement. We are also finalizing as proposed the enhancement to this payment methodology to permit MA EGWPs to buy down Part B premiums for their enrollees, using a portion of the Part C payment as described in Part II of the 2020 Advance Notice.

ESRD Risk Adjustment Models: We will implement the updated ESRD dialysis and ESRD functioning graft risk adjustment models as proposed in the Advance Notice. Therefore, for 2020 we will calculate risk scores as proposed in the Advance Notice. Specifically, we will blend 50% of the risk score using the 2019 ESRD models, using diagnoses from RAPS and FFS, summed with 50% of the risk score calculated with the 2020 ESRD models, using diagnoses from encounter data, RAPS inpatient records, and FFS. Attachment VI contains the risk adjustment factors for the 2020 ESRD dialysis and ESRD functioning graft models. For PACE organizations, we will continue to calculate ESRD risk scores using the 2019 ESRD dialysis and ESRD functioning graft models.

CMS-HCC Risk Adjustment Model Used for PACE Organizations: For 2020, we will use the 2017 CMS-HCC risk adjustment model and associated frailty factors to calculate risk scores for PACE organizations as proposed in the Advance Notice.

Adjustment for MA Coding Pattern Differences: We will implement an MA coding pattern difference adjustment of 5.90 percent for 2020.

Medical Loss Ratio Credibility Adjustment: We are finalizing continued use of the credibility adjustment factors as published in the Medical Loss Ratio final rule (CMS-4173-F), 78 FR 31284 (May 23, 2013).

Encounter Data as a Diagnosis Source for 2020 (non-PACE): As proposed, CMS will calculate 2020 risk scores by adding: (1) 50% of the risk score calculated (using the alternative payment condition count model) using diagnoses from encounter data (supplemented with diagnoses from RAPS inpatient data) and FFS data and (2) 50% of the risk score calculated (using the 2017 CMS-HCC model) using RAPS and FFS diagnoses.

Encounter Data as a Diagnosis Source for 2020 (PACE): As proposed, we will continue to calculate Part C, Part D and ESRD risk scores for PACE organizations by pooling risk adjustment-eligible diagnoses from encounter data, RAPS and FFS claims (with no weighting) to calculate a single risk score.

RxHCC Risk Adjustment Model: We will implement the RxHCC risk adjustment model recalibrated with 2014/2015 data as discussed in the Advance Notice. Attachment VI contains the risk adjustment factors for the 2014/2015 RxHCC model.

Part D Risk Sharing: As part of this final Rate Announcement, we are not making changes to the 2020 threshold risk percentages and payment adjustments for Part D risk sharing proposed in the Advance Notice.

Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2020: Attachment V provides the 2020 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

Part D Calendar Year Employer Group Waiver Plans: We are finalizing the Part D Calendar Year EGWP prospective reinsurance policy as proposed.

/ s /
Demetrios Kouzoukas
Principal Deputy Administrator
and Director, Center for Medicare

I, Jennifer Wuggazer Lazio, am a Member of the American Academy of Actuaries. I meet the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained in this Rate Announcement. My opinion is limited to the following sections of this Rate Announcement: The growth percentages and United States per capita cost estimates

provided and discussed in Attachments I, II and III; the qualifying county determination and calculations of Fee-for-Service cost, IME phase out, MA benchmarks, EGWP rates, and ESRD rates discussed in Attachment III; and Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2020 described in Attachments IV and V.

/ s /
Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary
Attachments

2020 RATE ANNOUNCEMENT TABLE OF CONTENTS

Attachment I. Final Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2020

The Table I-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2020. An adjustment of 1.40 percent for the combined aged and disabled is included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled change is used in the development of the ratebook.

Table I-1. Increase in the National Per Capita MA Growth Percentages for 2020

	Prior increases	Current increases			NPCMAGP for 2020 with §1853(c)(6)(C) adjustment[1]
	2003 to 2019	2003 to 2019	2019 to 2020	2003 to 2020	
Aged + Disabled	68.178 %	70.535 %	4.324 %	77.909 %	5.79 %

[1]Current increases for 2003-2020 divided by the prior increases for 2003-2019.

Table I-2 below provides the change in the FFS United States Per Capita Cost (USPCC) which was used in the development of the county benchmark. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2020 divided by projected FFS USPCC for 2019 as estimated in the 2019 Rate Announcement released on April 2, 2018.

Table I-2 – FFS USPCC Growth Percentage for CY 2020

	Aged + Disabled	Dialysis–only ESRD
Current projected 2020 FFS USPCC	$940.81	$7,795.38
Prior projected 2019 FFS USPCC	891.07	7,833.28
Percent change	5.58 %	-0.48 %

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2019 and 2020. In addition, for 2020, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2020. These data were furnished by the Office of the Actuary.

Table I-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2019 and 2020

	2019	2020	Change	2020 non-ESRD
Part A Benefits	$36.59	$36.72	0.4 %	$34.89
Part B Benefits[1]	133.57	140.46	5.2	130.28
Total Medicare	170.16	177.18	4.1	165.17

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2020 is $13,400.

Attachment II. Key Assumptions and Financial Information

The United States Per Capita Costs (USPCCs) are the basis for the National Per Capita MA Growth Percentage. Attached is a table that compares last year's estimates of USPCCs with current estimates for 2003 to 2021. In addition, this table shows the current projections of the USPCCs through 2022. We are also providing an attached set of tables that summarize many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2003 through 2022.

Most of the tables in this attachment present combined aged and disabled non-ESRD data. The ESRD information presented is for the combined aged-ESRD, disabled-ESRD and ESRD only.

All of the information provided in this attachment applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current & Previous Estimates of the Total USPCC – non-ESRD

	Part A		Part B		Part A + Part B		
Calendar year	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Ratio
2003	$296.18	$296.18	$247.66	$247.66	$543.84	$543.84	1.000
2004	314.08	314.08	271.06	271.06	585.14	585.14	1.000
2005	334.83	334.83	292.86	292.86	627.69	627.69	1.000
2006	345.30	345.30	313.70	313.70	659.00	659.00	1.000
2007	355.44	355.44	330.68	330.68	686.12	686.12	1.000
2008	371.90	371.90	351.04	351.04	722.94	722.94	1.000
2009	383.91	383.91	367.93	367.93	751.84	751.84	1.000
2010	383.94	383.95	376.79	376.81	760.73	760.76	1.000
2011	388.15	388.18	386.41	386.45	774.56	774.63	1.000
2012	377.72	377.72	392.97	392.97	770.69	770.69	1.000
2013	380.30	381.73	399.64	399.67	779.94	781.40	0.998
2014	372.59	372.77	418.60	418.59	791.19	791.36	1.000
2015	376.08	376.31	435.61	435.76	811.69	812.07	1.000
2016	379.90	380.07	445.63	446.33	825.53	826.40	0.999
2017	385.90	384.70	460.41	464.36	846.31	849.06	0.997
2018	391.41	390.02	493.05	488.79	884.46	878.81	1.006
2019	405.04	400.52	522.40	514.10	927.44	914.62	1.014
2020	419.00	412.19	548.54	537.91	967.54	950.10	1.018
2021	434.24	427.98	580.16	568.79	1,014.40	996.77	1.018
2022	452.61		612.18		1,064.79		

Comparison of Current & Previous Estimates of the FFS USPCC – non-ESRD

Calendar year	Part A		Part B		Part A + Part B		
	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Ratio
2010	$371.20	$371.20	$374.92	$374.92	$746.12	$746.12	1.000
2011	371.70	371.70	384.70	384.70	756.40	756.40	1.000
2012	357.52	357.52	392.25	392.25	749.77	749.77	1.000
2013	364.32	366.28	396.04	396.04	760.36	762.32	0.997
2014	367.61	367.40	409.50	409.08	777.11	776.48	1.001
2015	372.34	372.76	428.66	429.23	801.00	801.99	0.999
2016	374.82	374.86	435.52	436.55	810.34	811.41	0.999
2017	378.52	376.30	450.74	456.25	829.26	832.55	0.996
2018	385.24	381.58	482.87	474.83	868.11	856.41	1.014
2019	395.52	391.63	507.69	499.44	903.21	891.07	1.014
2020	409.27	403.45	531.54	523.29	940.81	926.74	1.015
2021	424.78	417.97	563.03	552.01	987.81	969.98	1.018
2022	442.49		593.81		1,036.30		

Comparison of Current & Previous Estimates of the ESRD Dialysis-only FFS USPCC

Calendar year	Part A		Part B		Part A + Part B		
	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Current estimate	Last year's estimate	Ratio
2010	$2,952.75	$2,952.75	$3,881.39	$3,881.39	$6,834.14	$6,834.14	1.000
2011	2,862.38	2,862.38	3,908.01	3,908.01	6,770.39	6,770.39	1.000
2012	2,774.49	2,774.49	3,944.59	3,944.59	6,719.08	6,719.08	1.000
2013	2,794.19	2,794.19	4,088.66	4,088.66	6,882.85	6,882.85	1.000
2014	2,784.52	2,784.52	4,115.70	4,115.70	6,900.22	6,900.22	1.000
2015	2,775.84	2,775.84	4,060.87	4,060.87	6,836.71	6,836.71	1.000
2016	2,895.91	2,895.91	4,081.27	4,081.27	6,977.18	6,977.18	1.000
2017	2,883.27	2,933.56	4,102.66	4,134.33	6,985.93	7,067.89	0.988
2018	2,928.10	3,148.72	4,459.82	4,437.56	7,387.92	7,586.28	0.974
2019	2,993.78	3,251.24	4,569.75	4,582.04	7,563.53	7,833.28	0.966
2020	3,098.04	3,361.57	4,697.34	4,737.54	7,795.38	8,099.11	0.962
2021	3,205.96	3,502.89	4,899.79	4,936.70	8,105.75	8,439.59	0.960
2022	3,327.60		5,109.43		8,437.03		

Basis for ESRD Dialysis-only FFS USPCC Trend

Calendar year	Part A			Part B			Part A & Part B		
	All ESRD cumulative FFS trend	Adjustment factor for dialysis-only	Adjusted dialysis-only cumulative trend	All ESRD cumulative FFS trend	Adjustment factor for dialysis-only	Adjusted dialysis-only cumulative trend	All ESRD cumulative FFS trend	Adjustment factor for dialysis-only	Adjusted dialysis-only cumulative trend
2018	1.02106	0.99460	1.01555	1.08359	1.00320	1.08706	1.05852	0.99908	1.05754
2019	1.04963	0.98923	1.03833	1.10676	1.00641	1.11385	1.08385	0.99892	1.08268
2020	1.09208	0.98389	1.07449	1.13403	1.00963	1.14495	1.11721	0.99880	1.11587
2021	1.13626	0.97857	1.11192	1.17913	1.01286	1.19430	1.16194	0.99858	1.16030
2022	1.18578	0.97329	1.15411	1.22566	1.01610	1.24539	1.20967	0.99839	1.20772

Summary of Key Projections

Part A[1]

Year	Calendar year CPI percent change	FY inpatient PPS update factor	FY Part A total reimbursement (incurred)
2003	2.2%	3.0%	3.5%
2004	2.6	3.4	8.4
2005	3.5	3.3	8.8
2006	3.2	3.7	5.9
2007	2.9	3.4	5.7
2008	4.1	2.7	7.6
2009	−0.7	2.7	6.7
2010	2.1	1.9	3.0
2011	3.6	−0.6	4.5
2012	2.1	−0.1	0.4
2013	1.4	2.8	4.7
2014	1.5	0.9	1.0
2015	−0.4	1.4	3.3
2016	1.0	0.9	4.2
2017	2.1	0.2	3.8
2018	2.6	1.8	4.0
2019	1.8	1.9	5.5
2020	2.6	4.0	6.6
2021	2.6	3.8	6.6
2022	2.6	3.6	7.1

Part B[2]

Calendar year	Physician fee schedule		Outpatient hospital	Total
	Fees[3]	Residual[4]		
2003	1.4%	4.5%	4.4%	6.8%
2004	3.8	5.9	11.1	9.8
2005	2.1	3.2	10.8	7.0
2006	0.2	4.6	5.1	6.1
2007	−1.4	3.5	8.3	4.3
2008	−0.3	4.0	6.3	4.8
2009	1.4	1.6	5.7	4.0
2010	2.3	1.6	6.6	2.4
2011	0.8	2.3	7.1	2.3
2012	−1.2	1.0	7.2	1.7
2013	−0.1	0.2	7.2	0.8
2014	0.4	0.7	12.4	3.4
2015	−0.3	0.5	7.3	2.7
2016	−0.4	−0.9	5.4	1.9
2017	0.1	0.8	7.5	2.8
2018	0.5	1.8	9.4	6.0
2019	1.3	1.6	6.7	5.1
2020	−0.6	2.5	9.3	4.7
2021	0.0	2.5	9.3	5.6
2022	0.0	2.8	9.3	5.5

[1] Percent change over prior year.
[2] Percent change in charges per aged Part B enrollee.
[3] Reflects the physician update and all legislation affecting physician services—for example, the addition of new preventive services enacted in 1997, 2000, and 2010.
[4] Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections (In millions)

Non-ESRD Total

	Part A		Part B	
Calendar year	Aged	Disabled	Aged	Disabled
2003	34.437	5.961	33.038	5.215
2004	34.849	6.283	33.294	5.486
2005	35.257	6.610	33.621	5.776
2006	35.795	6.889	33.975	6.017
2007	36.447	7.167	34.465	6.245
2008	37.378	7.362	35.140	6.438
2009	38.257	7.574	35.832	6.664
2010	39.091	7.832	36.516	6.938
2011	39.950	8.171	37.247	7.254
2012	41.687	8.411	38.546	7.502
2013	43.087	8.629	39.779	7.732
2014	44.533	8.776	41.064	7.894
2015	45.911	8.852	42.311	7.976
2016	47.371	8.860	43.624	7.988
2017	48.898	8.765	44.939	7.936
2018	50.549	8.507	46.284	7.786
2019	52.120	8.353	47.750	7.612
2020	53.803	8.338	49.257	7.573
2021	55.512	8.399	50.781	7.594
2022	57.282	8.406	52.362	7.587

Non-ESRD Fee-for-Service

	Part A		Part B	
Calendar year	Aged	Disabled	Aged	Disabled
2003	29.593	5.628	28.097	4.875
2004	29.946	5.931	28.300	5.128
2005	30.014	6.178	28.287	5.339
2006	29.365	6.146	27.462	5.267
2007	28.838	6.226	26.782	5.297
2008	28.613	6.241	26.301	5.311
2009	28.563	6.288	26.071	5.374
2010	28.903	6.455	26.261	5.556
2011	29.210	6.659	26.440	5.736
2012	29.960	6.693	26.744	5.779
2013	30.330	6.691	26.948	5.790
2014	30.603	6.618	27.060	5.732
2015	30.948	6.489	27.274	5.609
2016	31.630	6.378	27.815	5.502
2017	31.922	6.125	27.878	5.290
2018	32.259	5.686	27.900	4.960
2019	32.529	5.382	28.105	4.639
2020	33.214	5.228	28.611	4.460
2021	34.155	5.211	29.366	4.404
2022	35.113	5.103	30.133	4.281

ESRD

Calendar year	ESRD - Total		ESRD - Fee-for-Service	
	Total Part A	Total Part B	Total Part A	Total Part B
2003	0.340	0.331	0.319	0.309
2004	0.353	0.342	0.332	0.321
2005	0.366	0.355	0.344	0.332
2006	0.382	0.370	0.353	0.340
2007	0.396	0.383	0.361	0.347
2008	0.411	0.397	0.367	0.353
2009	0.426	0.412	0.374	0.360
2010	0.442	0.428	0.388	0.373
2011	0.429	0.416	0.371	0.358
2012	0.441	0.429	0.379	0.366
2013	0.454	0.441	0.385	0.372
2014	0.469	0.456	0.390	0.377
2015	0.483	0.469	0.394	0.380
2016	0.497	0.482	0.401	0.385
2017	0.510	0.494	0.402	0.386
2018	0.521	0.505	0.401	0.384
2019	0.532	0.516	0.401	0.384
2020	0.546	0.529	0.408	0.391
2021	0.559	0.542	0.415	0.397
2022	0.572	0.554	0.421	0.402

Part A Projections for non-ESRD (Aged+Disabled)

Calendar year	Inpatient hospital	SNF	Home health agency	Managed care	Hospice: Total reimbursement (in millions)
2003	2,594.78	370.63	124.28	457.87	5,733
2004	2,714.57	413.44	133.89	500.73	6,832
2005	2,818.21	450.54	140.87	602.29	8,016
2006	2,764.82	475.07	141.30	757.20	9,368
2007	2,707.49	504.24	143.72	905.77	10,518
2008	2,695.88	536.68	151.00	1,075.01	11,404
2009	2,651.47	551.67	153.86	1,246.03	12,274
2010	2,627.03	571.74	155.18	1,249.71	13,126
2011	2,585.95	623.31	143.31	1,299.29	13,986
2012	2,489.44	541.69	135.64	1,359.47	15,163
2013	2,485.38	540.47	133.29	1,398.06	15,356
2014	2,445.23	536.73	128.93	1,353.92	15,510
2015	2,425.99	533.42	130.99	1,416.92	16,237
2016	2,445.90	507.54	126.31	1,475.20	17,230
2017	2,428.80	488.86	122.63	1,586.64	18,310
2018	2,414.66	475.68	122.71	1,679.97	19,458
2019	2,390.83	475.08	124.82	1,865.68	20,889
2020	2,436.93	489.14	127.90	1,969.85	22,690
2021	2,512.37	509.72	134.10	2,050.29	24,598
2022	2,594.01	533.33	140.72	2,158.73	26,615

Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections for non-ESRD (Aged+Disabled)

Calendar year	Physician fee schedule	Outpatient hospital	Durable medical equipment
2003	1,226.49	364.77	196.96
2004	1,343.99	418.85	195.61
2005	1,397.41	477.65	196.83
2006	1,396.39	497.47	197.78
2007	1,368.35	526.92	195.68
2008	1,367.83	555.09	200.92
2009	1,375.29	592.77	183.61
2010	1,413.77	628.55	183.76
2011	1,442.78	668.57	175.83
2012	1,398.89	703.65	173.70
2013	1,356.05	741.35	152.53
2014	1,337.86	821.95	128.59
2015	1,340.18	873.92	132.81
2016	1,310.83	912.86	121.12
2017	1,282.58	956.66	112.57
2018	1,307.52	1,005.56	128.78
2019	1,312.10	1,050.84	128.62
2020	1,313.64	1,125.82	131.66
2021	1,337.36	1,221.90	140.93
2022	1,351.98	1,324.00	145.47

Calendar year	Carrier lab	Physician Administered Drugs	Other carrier	Intermediary lab
2003	73.73	182.58	147.22	75.18
2004	78.48	195.20	158.80	80.47
2005	82.71	178.77	184.04	84.16
2006	85.59	185.41	175.66	84.51
2007	90.65	186.97	176.55	84.38
2008	94.50	184.43	182.19	85.78
2009	101.80	192.97	192.23	79.19
2010	101.08	197.62	196.16	80.23
2011	102.19	209.43	197.86	83.31
2012	109.72	205.31	205.02	84.64
2013	109.32	212.00	197.68	81.74
2014	114.60	216.67	195.09	55.45
2015	114.63	228.59	195.08	55.26
2016	107.04	250.35	197.81	56.21
2017	107.03	261.06	206.35	55.08
2018	110.16	289.00	205.07	53.17
2019	102.68	305.42	205.11	47.56
2020	98.51	325.50	207.14	44.25
2021	109.26	350.40	212.57	47.68
2022	113.90	376.10	218.40	48.37

Average reimbursement per enrollee on an incurred basis, except where noted.

Calendar year	Other intermediary	Home health agency	Managed care
2003	113.99	136.75	421.40
2004	119.58	156.45	471.37
2005	139.78	179.44	560.31
2006	142.09	202.88	769.94
2007	151.16	232.33	931.18
2008	158.20	252.43	1,104.26
2009	187.44	282.09	1,203.81
2010	193.08	283.25	1,221.30
2011	198.15	262.22	1,276.30
2012	205.08	246.70	1,367.53
2013	194.43	241.20	1,495.81
2014	200.42	234.73	1,703.41
2015	209.88	231.61	1,831.18
2016	213.63	225.81	1,939.35
2017	221.44	215.46	2,095.04
2018	233.62	215.93	2,356.20
2019	238.41	219.33	2,646.53
2020	247.78	224.81	2,850.58
2021	260.28	235.88	3,032.04
2022	272.96	247.69	3,233.01

Average reimbursement per enrollee on an incurred basis, except where noted.

2020 Projections by Service Category for non-ESRD (Aged+Disabled)

Service type	Current estimate	Last year's estimate	Ratio
Part A			
Inpatient hospital	$2,436.93	$2,458.39	0.991
SNF	489.14	512.83	0.954
Home health agency	127.90	133.69	0.957
Managed care	1,969.85	1,837.30	1.072
Part B			
Physician fee schedule	1,313.64	1,372.31	0.957
Outpatient hospital	1,125.82	1,153.04	0.976
Durable medical equipment	131.66	128.26	1.027
Carrier lab	98.51	91.42	1.078
Physician Administered Drugs[1]	325.50	N/A	N/A
Other carrier[1]	207.14	506.99	N/A
Intermediary lab	44.25	44.84	0.987
Other intermediary	247.78	246.11	1.007
Home health agency	224.81	238.88	0.941
Managed care	2,850.58	2,659.53	1.072

Average reimbursement per enrollee on an incurred basis, except where noted.

[1] In the current estimate, the Physician Administered Drugs category has been removed from the Other Carrier category and is shown separately. In Last Year's estimate, the Physician Administered Drugs is included in the Other Carrier category.

Claims Processing Costs as a Fraction of Benefits

Calendar year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000844	0.005455
2010	0.000773	0.005055
2011	0.000749	0.004396
2012	0.001008	0.003288
2013	0.000994	0.002846
2014	0.001003	0.002884
2015	0.000952	0.002730
2016	0.000852	0.002348
2017	0.000833	0.002111
2018	0.000836	0.001953
2019	0.000836	0.001953
2020	0.000836	0.001953
2021	0.000836	0.001953
2022	0.000836	0.001953

Approximate Calculation of the USPCC, the National MA Growth Percentage for Combined (Aged+Disabled) Beneficiaries, and the FFS USPCC (Aged+Disabled)

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:

The Part A USPCC can be approximated by using the assumptions in the tables titled “Part A Projections under Present Law for non-ESRD (Aged+Disabled)” and “Claims Processing Costs as a Fraction of Benefits.” Information in the “Part A Projections” table is presented on a calendar year per capita basis. First, add the per capita amounts over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the “Claims Processing Costs” table. Then, divide by 12 to put this amount on a monthly basis.

Part B:

The Part B USPCC can be approximated by using the assumptions in the tables titled “Part B Projections under Present Law for non-ESRD (Aged+Disabled)” and “Claims Processing Costs as a Fraction of Benefits.” Information in the “Part B Projections” table is presented on a calendar year per capita basis. First, add the per capita amounts over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis.

The National Per Capita MA Growth Percentage:

The National Per Capita MA Growth Percentage for 2020 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2020 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2019.

The FFS USPCC:

The tables used to calculate the total USPCC can also be used to approximate the calculations of the FFS USPCC. The per capita data presented by type of provider in the projections tables for both Part A and B are based on total enrollment. To approximate the FFS USPCCs, first add the corresponding provider types under Part A and Part B separately. For the FFS calculations, do not include the managed care provider type. Next, rebase the sum of the per capita amounts for FFS enrollees, i.e., multiply the sum by total enrollees and divide by FFS enrollees. (The enrollment tables in this attachment now also include FFS enrollment). Then, multiply by 1 plus the loading factor for administrative expenses and divide by 12. The result will only be approximate because there is an additional adjustment to the FFS data which accounts for cost plan data which comes through the FFS data system. This cost plan data is in the total per capita amounts by type of provider, but is removed for the FFS calculations.

Attachment III. Responses to Public Comments

Section A. Estimates of the MA and FFS Growth Percentages for 2020

Comment: Two commenters expressed appreciation for the timely and detailed information released regarding the growth percentages, and encouraged CMS to continue to share more granular information regarding the underlying methodology and analyses related to the growth percentages and the development of the county benchmarks.

Response: We appreciate the support. With the final Rate Announcement, we annually publish detailed information regarding the growth percentages. We believe that this provides useful information and support pertaining to USPCC levels and trends. Key economic assumptions underlying the USPCCs are included in Attachment II of this Rate Announcement. Also, consistent with prior years, we will publish additional information regarding trends for the prior five years at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Trends.html. We will consider publishing additional information in future years that can help interested parties understand the potential impacts of changes.

Comment: One commenter noted that calendar year 2020 is a leap year, with an additional business day, and provided an estimate of the expected resulting increase in utilization of services. The commenter requested that CMS take this into account when determining the claims trend assumptions.

Response: We appreciate the feedback submitted by the commenter regarding this issue. CMS's projection of Medicare fee-for-service (FFS) expenditures takes into account many factors including changes in population, payment rates, utilization, case mix, legislation, and regulations. Our projection methodology does not account for the number of business days in each period. We may consider modifying our methodology in future years to project Medicare FFS expenditures to include the number of business days for each period.

Comment: One commenter expressed concern with including beneficiaries enrolled in Part A only in the calculation of the USPCCs that determine the MA growth percentage, the FFS growth percentage, and the ESRD payment rates. The commenter recommended that CMS calculate FFS spending used in the USPCCs, county benchmarks, and ESRD state rates based on beneficiaries enrolled in both Parts A and B. The commenter further stated that the risk adjustment models are calibrated with FFS beneficiaries enrolled in Part A and Part B, and recommended that risk adjustment and payment rates be based on the same population.

Response: We address this issue in more detail in response to similar comments in Section C "Calculation of Fee-for-Service Cost" of this document. The county-level or state FFS rates are calculated, in part, using the FFS USPCC growth percentages.

Comment: One commenter noted that the proposed ESRD growth rate for 2020 was smaller than the non-ESRD growth rates, and requested that CMS publish the underlying Part A and Part B cost data for the ESRD population, similar to the information that was released for the non-ESRD population in Table I-3 of the 2020 Advance Notice Part II. Another commenter also requested more transparency regarding the development of the ESRD growth rates. One commenter expressed concern regarding the volatility of the ESRD growth rate.

Response: With the final Rate Announcement, we annually publish detailed information regarding the growth percentages to provide useful information and support pertaining to ESRD dialysis-only FFS USPCC levels and trends. Attachment II of this Rate Announcement contains the comparison of current and previous estimates of the ESRD dialysis-only FFS USPCC for Part A and Part B, as well as the Part A and Part B historical trends and adjustment factors, in order to provide commenters with additional details regarding annual changes in the ESRD growth rate. Also, consistent with prior years, we will publish the ESRD dialysis-only Part A and Part B data at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html, (see the link for "USPCC as of April 2019"). We will consider publishing additional information with the Advance Notice in future years that can help interested parties understand the proposed changes.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: A large number of commenters expressed concern that the pre-ACA rate cap diminishes incentives for high quality plans. Commenters believe that the inclusion of the quality bonus in the rate cap calculation undermines the quality bonus program. Commenters also indicated that the cap methodology could reduce benefits to beneficiaries in high quality plans. One commenter indicated that the benchmark cap makes it difficult for plans to utilize new benefit flexibility, expand supplemental benefits available to enrollees, and otherwise offer innovative plan designs that best serve beneficiaries' needs. Commenters expressed concern that the cap is inconsistent with the agency's goals of encouraging plans to continuously improve the quality of care provided to enrollees, and rewarding the delivery of high quality care. A commenter indicated that the benchmark cap adversely affects plans with high cost enrollees, such as dual-eligible beneficiaries and beneficiaries with ESRD.

Commenters suggested that we review our options for exercising discretionary, regulatory, and/or demonstration authority to eliminate the cap or to remove quality bonuses from the cap calculation, or to find other ways to reward high quality plans. Commenters noted legal analyses provided to CMS in previous years regarding this issue.

Response: While we appreciate the concerns of commenters, we have not identified discretion under section 1853(n)(4) of the Act to eliminate application of the pre-ACA rate cap or exclude the bonus payment from the cap calculation.

Comment: One commenter expressed support for the proposed continuation of policy for determining the quality bonus payment percentage increase to county rates. Another commenter suggested that CMS work with Congress to change the current bonus and rebate retention structure to include a bonus for 3.5 Star plans, decrease the rate differences between 3.5 and 4 Star plans, and reduce the rebate retention difference between 3.0 and 3.5 Star plans. The commenter further suggested that CMS develop a demonstration to smooth out the bonus payment structure and to reinstate a rebate retention percentage of 75% for all Star levels.

Response: We appreciate the feedback submitted by commenters regarding this issue.

Comment: Several commenters expressed support for CMS's determination that some of the counties in Puerto Rico will be eligible for the Qualifying County Bonus Payment in 2020. One of the commenters further requested that all 78 counties in Puerto Rico be classified as qualifying counties, suggesting that the 2004 Urban Floor criteria should be based on the entire territory, suggesting that MSA delineations may be modified by the agency based on an OMB Bulletin dated February 28, 2013.

Response: As indicated in the Advance Notice, section 1853(o)(3)(B) of the Act provides the criteria for determining a qualifying county. We do not have discretion to reclassify counties that do not meet the statutory criteria as qualifying counties for the double bonus payment. The counties in Puerto Rico that are not classified as qualifying counties are the counties that do not meet the criteria that the county's 2004 MA capitation rate was based on the amount specified in section 1853(c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000.

Section C. Calculation of Fee-for-Service Cost

Comment: A large number of commenters requested that we calculate FFS spending using only claims and utilization data for beneficiaries enrolled in both Part A and Part B (rather than based on such data for beneficiaries in Part A and/or Part B) on the basis that it would be a more accurate, reasonable, appropriate, and/or equitable methodology. Commenters pointed out that in order to enroll in an MA plan, beneficiaries are required to be enrolled in both Part A and Part B; commenters stated that the FFS cost estimates used for setting payment to MA plans should be calculated consistently with MA coverage in order to ensure that it is representative of the expected spending. A commenter stated that, over time, as a higher percentage of beneficiaries join MA plans, a higher percentage of beneficiaries remaining in FFS do not enroll in Part B. Commenters expressed concern that increasing MA penetration leaves fewer, and a less representative population of, beneficiaries on which to calculate FFS spending. Commenters noted that beneficiaries enrolled in Part A-only had lower Part A spending than beneficiaries enrolled in both Part A and Part B, and requested excluding Part A-only beneficiaries from the methodology. Two commenters stated that the risk adjustment models are calibrated with FFS beneficiaries enrolled in Part A and Part B, and recommended that risk adjustment and payment

rates be based on the same population. Commenters cited MedPAC's recommendation that benchmarks be calculated based on FFS data for beneficiaries with both Part A and Part B, and a related Health Affairs Blog article on this topic.

Commenters requested that we apply a uniform approach in all counties to calculate benchmarks using FFS per capita projections based only on Original [FFS] Medicare costs for beneficiaries with both Part A and Part B coverage, as is currently done in Puerto Rico. One commenter noted that other counties beyond Puerto Rico, such as in Hawaii, have high MA penetration rates and low FFS Part B enrollment. Several commenters expressed support that the benchmarks in Puerto Rico be based on the Medicare costs for beneficiaries with both Part A and Part B coverage.

One commenter referred to actuarial principles regarding per capita rates representing what Medicare would have spent under traditional FFS Medicare. The commenter noted that the current methodology of calculating separate Part A and Part B per capita cost estimates and then summing them together does not result in the same per capita cost estimate calculated using claims and utilization data for beneficiaries with both Parts A and B. The commenter believes that, from an actuarial perspective, this methodology is not valid since the total rate obtained by summing the separate Part A per capita rate and Part B per capita rate does not yield the same result as the rate calculated using beneficiaries with both Parts A and B. Commenters performed an analysis of published claim costs and concluded that the differences in costs are material and stated that the average per capita costs for a beneficiary with both Parts A and B are 4 to 5 percent higher than the average per capita costs for a beneficiary with Part A and/or B, and noted that the differences can be higher in particular counties. Since the differences in these costs are considered material, the commenter believes that actuarial principles require calculating the benchmarks by excluding Part A-only enrollees from the calculation.

Two commenters noted that previous Rate Announcements have indicated that CMS would continue to analyze this issue and consider whether adjustment may be warranted, but the 2020 Advance Notice did not provide any further analysis or discussion of this topic. Another commenter requested that CMS provide thorough analysis and rationale in the Rate Announcement. Two commenters noted legal analysis previously provided to CMS regarding this issue, which interpreted that the statute compels the exclusion of Part A-only enrollees from the calculation of county benchmarks. One commenter specifically stated that CMS must, in response to public comments, provide a legal analysis of the statutory language and construction that demonstrates that CMS has clear authority to include Part A-only enrollees in the calculation and is not acting in an arbitrary manner.

Response: As noted in Rate Announcements since 2012, section 1853(n)(2) requires the use of an estimate of per capita FFS costs in the development of MA benchmarks for each MA service area. Section 1853(n)(2)(E) defines the "base payment amount" by reference to subsection (c)(1)(D). In a rebasing year, the base payment amount is the amount specified in subsection

(c)(1)(D); in a year that is not a rebasing year, the base payment amount is the amount calculated for the previous year increased by the national per capita MA growth percentage.

Under the heading, "100 percent of fee-for-service costs," subsection (c)(1)(D) specifies use of "the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year," with specific adjustments involving incentives related to meaningful use of EHR, payments for direct graduate medical education costs, and an estimate of per capita costs related to services provided by facilities of the Department of Defense or the Department of Veterans Affairs. Section 1853(n)(2)(F) and (K) address other required adjustments. The statute requires that the per capita cost be determined under section 1876(a)(4), which provides discretion to the Secretary in identifying and using appropriate data for purposes of developing the estimate.

We recognize that commenters, including MedPAC, have expressed concerns that using a slightly different scope of FFS data for calculating the AAPCC in Puerto Rico raises "equity issues" (MedPAC Report to Congress, Chapter 13, March 2017, p. 347) and concerns that MA benchmarks are based what the commenters believe to be underestimated FFS costs. We do not believe that it is necessary or required to change the methodology at this time, however. We note that section 1853(c)(1)(D) requires that the estimate be "for individuals who are not enrolled in an MA plan" for the applicable area for the year. This language clearly permits CMS to include Medicare beneficiaries who have Part A or Part B only. The commenters challenging our authority to continue use of the existing methodology fail to address this language, but instead cite language in section 1876(a)(4) referring to coverage and expenses under Part A and B or Part B only. This language in section 1876 dates to a time prior to the enactment of Medicare Part C when both cost and risk contracts were governed by section 1876. At that time, enrollment in a risk contract was permissible if an individual had Part A and B, or Part B only, but not if the individual had only Part A. We do not believe it would be legally required to apply this language the way that the commenters have recommended in the context of Part C.

We also note that section 1876(a)(4) explicitly refers to use of actual experience or an adequate sample; by using data from the FFS Medicare program, with the adjustments we have developed in refining our methodology, we believe that our current methodology is well within the latitude provided in the statute for how the estimate is developed.

Further, since the adjusted average per capita cost (AAPCC) was first used in establishing payment amounts for risk contracts in 1985, CMS has used substantially the same methodology, which starts with all Medicare FFS data, even though section 1876(a)(4) made reference to Part A and B or Part B only. *See* Medicare Program; Standardized Per Capita Rate of Payments for Health Maintenance Organizations and Competitive Medicare Plans for 1986, 51 FR 506 (Jan. 6, 1986). Although CMS has adopted a number of refinements to the methodology since the AAPCC has been incorporated into MA payment policy, e.g., CY 2012 Rate Announcement

(excluding hospice claims in calculating the AGA, excluding cost plan data in calculating both the USPCC and the AGA, and using claims for beneficiaries with both Part A and Part B in calculating the AAPCC for service areas in Puerto Rico), we remain convinced that the methodology is sound and within the agency's discretion to use the population with A and/or B, with the established adjustments.

While we recognize that calculating rates based on data that excludes beneficiaries entitled only to Part A would yield different results than calculating rates based on our current methodology, that fact alone does not determine which methodology should be employed. We have discussed in past Advance Notices and Rate Announcements that while most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in Puerto Rico must take affirmative action to opt-in to Part B coverage. As a result, we believe it is appropriate to adjust the FFS rate calculation for Puerto Rico used to determine MA rates so that it is based only on the Medicare costs for beneficiaries with both Part A and Part B. Our exercise in discretion for the data used to develop the estimate for one geographic area, based on circumstances unique to that area, illustrates how there is more than one way to develop a reasonable and reliable adjusted average per capita cost estimate for purposes of the MA statute. We appreciate the suggestions submitted by commenters, and we will continue to analyze this issue and consider whether any adjustments to the methodology on this point may be warranted in future years. CMS provides public notice and a comment period via the Advance Notice and Rate Announcement process, in order to provide all stakeholders with an opportunity to consider the impacts of potential changes to the program and provide input prior to implementation.

Comment: Two commenters supported the continued refinements and repricing of the FFS cost calculation, but requested that any methodological changes to the AGA calculation should be scheduled on a regularly occurring basis (such as every three years), rather than annually, to promote stability in rates.

Response: As discussed in past Rate Announcements, given that MA county rates are based on FFS costs, we believe it is important to update the FFS per capita cost estimates using the most current FFS data available and apply repricing adjustments to reflect changes in FFS payment rules. We have stated in previous Rate Announcements that we anticipate rebasing each year, and that the method for calculating the county level rates includes a five-year rolling average of historical claims experience which provides some measure of stability in the rates.

Comment: One commenter noted the Advance Notice stated that "the average of the five year geographic indices, based on the adjusted claims data, will be divided by the county's average five-year risk score from the 2020 risk model in order to develop the AGA for that county". The commenter pointed out that this language appeared to indicate that benchmarks would be standardized using only the new 2020 risk model proposed in the Advance Notice, and would be inconsistent with the Advance Notice proposal to phase in a new 2020 risk model.

Response: We clarify that the benchmarks will be standardized with the risk model being used for 2020 payment, including any blending/phase-in of the risk adjustment models.

Comment: One commenter expressed appreciation for the publication of 2017 FFS costs with the Advance Notice, and further requested that we publish an initial estimate of the county rates with the Advance Notice.

Response: Pursuant to section 1853(b)(2) of the Act, we provide an explanation of any proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement. Due to the timing constraints in when most recent Medicare FFS data is available and given that some data and assumptions will not be available at that time, it is unlikely that we will be in position to publish an estimate of the county rates in conjunction with future Advance Notices. We will consider publishing additional information in future years that can help interested parties understand the potential impacts of proposed changes in the Advance Notice.

Comment: One commenter requested information regarding the methodology used to account for the 5 percent provider bonus payments under Alternative Payment Models (APM) and payments from the Merit-based Incentive Payment System (MIPS) in the county benchmark calculation. The commenter expressed concern about assessing the impact of adjustments for demonstrations and ACO shared savings and losses.

Response: As discussed in the CY 2019 Advance Notice (page 7) and CY 2019 Rate Announcement (page 24), APM incentive payments and MIPS payment adjustments made to providers pursuant to Part B payment rules will be reflected in CMS's FFS claims experience. Although the 2020 Advance Notice did not reference these specific adjustments to FFS payments by name, we are continuing to include these as part of the Medicare FFS payment, consistent with the policy adopted in the most recent FFS payment rules. Thus, the payments will be represented in the FFS claims tabulations supporting the development of the ratebook average geographic adjustment (AGA) index and the corresponding FFS per capita cost estimate. Further, the aggregate impact of APM and MIPS payments are reflected in the FFS and total USPCCs. We will consider publishing additional information in future years that can help interested parties understand the potential impacts of changes.

In addition, we are specifying the inclusion of certain fees paid in one CMS Innovation Center model in our adjustment of historical FFS claims experience. We stated in the Advance Notice that care management fees would not be accounted for in the adjustments to historical FFS experience when they were funded from other sources (that is, when they're not funded by Medicare Trust Funds). Specifically, we note that since the Care Management Fees (CMFs) for the Comprehensive Primary Care Plus (CPC+) model are paid out of the Part B Trust Fund, the CPC+ model Care Management Fees will be included in the adjustments to historical FFS claims experience, consistent with the approach described in the Advance Notice.

Comment: Two commenters expressed concern regarding how CMS adjusts payments to account for changes in Medicare Disproportionate Share Hospital (DSH) payments and uncompensated care payments (UCP). The commenters stated that, beginning in FY 2018, CMS implemented a three-year transition period that would phase out the use of proxy low-income days in the calculation and shifted to using uncompensated care data from Medicare Cost Report Worksheet S-10. The commenters indicated that due to this three-year phase-in, FY 2019 and FY 2020 will be calculated differently and basing the 2020 AGA on the FY 2019 UCP calculation causes a lag whereby the AGA would not reflect the appropriate costs for 2020. The commenters requested that CMS consider modifying the AGA calculation for MA payment year 2020 such that the historical claims data that is used to determine the AGA be adjusted to solely reflect Worksheet S-10 data. The commenters indicated that making this change would ensure that the geographic redistribution associated with this FFS policy change is reflected in the benchmark and ensure that 2020 MA rates align with expected DSH payment adjustments in 2020.

Response: We thank the commenters for their recommendation on this issue. However, this recommendation is not consistent with our practice of basing the repricing adjustments on the law and regulations in effect at the time the estimate is made. We review and use information from applicable final rules governing payment in the FFS Medicare program in repricing FFS claims used to develop the per capita cost estimate (in this case, the FY 2019 Hospital Inpatient Prospective Payment System final rule, CMS-1694-F (83 FR 41144 (Aug, 17, 2018), in which CMS adopted a final policy governing the calculation of UCP for FY 2019, but did not adopt any final policy with respect to the calculation of UCP for FY 2020). Therefore, this recommendation will not be adopted.

Comment: One commenter expressed support for the proposed repricing methodology to incorporate updated wage and cost indices and legislative and regulatory rules, and requested that CMS consider the injunction against CMS's discounted ASP-22.5% pricing for 340B-acquired drugs when repricing historical claim experience.

Response: We thank the commenter for their recommendation on this issue. CMS did not propose to reprice Part B physician administered drugs in the 2020 Advance Notice and we have not developed the data and systems to support such repricing. Therefore, the 2020 ratebook FFS costs will not reflect the impact of repricing historical Part B physician administered drugs, including 340B acquired drugs.

Comment: The Advance Notice sought public comment on the possibility of adjusting FFS experience in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide. A large number of commenters requested that we make an adjustment to the Puerto Rico MA rates to reflect the prevalence of zero dollar beneficiaries nationwide.

Response: The Secretary has directed the Office of the Actuary to adjust the FFS experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of zero dollar beneficiaries nationwide. For purposes of making this adjustment, consistent with the Secretary's instructions, the Office of the Actuary evaluated experience exclusively for beneficiaries that are enrolled in both Parts A and B and are not also eligible for VA coverage.

The updated study analyzed experience for calendar years 2013 through 2017 and only considered FFS beneficiaries enrolled mid-year. On average, 14.9 percent of A&B Puerto Rico FFS beneficiaries were found to have no Medicare claim reimbursements per year. This compares to a nationwide, non-territory, proportion of 6.1 percent of FFS beneficiaries without Medicare spending. These results were applied to the Puerto Rico FFS experience by adjusting the weighting of the enrollment and risk scores for the zero-claim cohort to reflect the nationwide proportion of zero-claim beneficiaries. The resulting impact was an average increase in the standardized FFS costs in Puerto Rico of 4.7 percent for 2013 through 2017. Accordingly, a 4.7 percent adjustment was applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2020 ratebook development.

Comment: A number of commenters requested that we adjust the MA rates in Puerto Rico for any data anomalies, deficiencies, and/or fluctuations, particularly in light of hurricane disasters in 2017. One commenter supported the proposed use of five years of FFS experience to mitigate annual fluctuations and anomalies in the data.

One commenter noted that the Advance Notice mentioned an analysis of trends in the 2017 FFS data that found that counties beyond Puerto Rico (including counties not impacted by any natural disasters) also experienced decreases in per-capita costs in 2017. The commenter indicated that this information did not provide details of this analysis, such as the magnitude of the impacts and the time interval at which the analysis was conducted (annual/ quarterly/monthly). Also, the commenter suggested that the impact of the hurricane may be masked by other changes in the 2017 FFS data (for example, changes in the Medicare FFS physician fees and uncompensated care payments).

Two commenters indicated that the duration and severity of Hurricane Maria on Puerto Rico's health care system was unlike any other prior disaster and therefore warrants a change in ratebook methodology, such as extrapolating 2017 FFS experience.

Response: As indicated in the Advance Notice, we reviewed trends in the 2017 FFS data. We reviewed per-member per-month spending for all FFS beneficiaries, including those with coverage for Part A only and Part B only, during calendar years 2016 and 2017 at several levels (ex: county-level). We compared 2016-2017 trends relative to other jurisdictions. We found that while some counties in Puerto Rico did experience decreased per-capita costs, we noted that other counties beyond Puerto Rico, including counties that were not affected by natural disasters, also experienced decreased per-capita costs. Based on our analysis of these results, we have

concluded that no adjustment to claims in Puerto Rico, or another jurisdiction, due to 2017 natural disasters is necessary.

A comparable study could be prepared by stakeholders using published ratebook FFS experience for 2016 and 2017, using the files FFS16.xlsx and FFS17.xlsx available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html, see tab "FFS Data (2015-2017)", with the following considerations and data fields.

- Using data from FFS16.xlsx, calculate 2016 per-capita spending for Medicare Parts A and B for each county: sum of fields "Part A Total Per Capita" and "Part B Total Per Capita."
- Using data from FFS17.xlsx, calculate 2017 per-capita spending for Medicare Parts A and B for each county: sum of fields "Part A Total Per Capita" and "Part B Total Per Capita."
- Calculate 2017 county level Part A and Part B per capita trend: (2017 per-capita spending for Medicare Parts A and B) / (2016 per-capita spending for Medicare Parts A and B) – 1
- Compare 2017 annual trend for specific counties relative to other counties.
- In the development of the cohort of counties to include in the trend analysis, consideration should be given to limiting counties to those with a minimum level of credibility. The full credibility threshold is 1,000 average Part B members and the formula for credibility is: (average Part B enrollment for 2016 and 2017 / 1,000) ^ (0.5), not to exceed 1.0.
    - Thus, limiting the analysis to counties with credibility of 75 percent or greater would include only counties with 563 or greater average Part B FFS beneficiaries enrolled during 2016 and 2017. The corresponding calculation is (563 / 1000) ^ (0.5) = 0.750

Comment: One commenter noted the county assignment of FFS claims and enrollment used in the ratebook methodology and had several questions pertaining to Puerto Rico, seeking additional information pertaining to the methodology used for beneficiaries that had temporary addresses in the mainland stemming from the impact of Hurricane Maria, the adjudication of claims for Medicare A/B enrollees that had moved to the mainland, and how total United States costs were considered in the Puerto Rico 2017 per-capita cost experience.

Response: The historical enrollment and claims supporting the ratebook FFS rates are assigned to counties based on each beneficiary's permanent address on file with the Social Security Administration (SSA), not based on the location where the service is provided. The county level assignment of claims is based on the address on file with SSA, not the location of the provider or a temporary location of the beneficiary. Analysis of FFS enrollment in Puerto Rico indicates that there was not an unusual change in the number of enrollees in 2017 relative to earlier years. The FFS enrollment in Puerto Rico increased by an average of 500 beneficiaries for the three months

following Hurricane Maria, October 2017 – December 2017. This change is comparable to the average enrollment increase for counties in Puerto Rico during October 2015 – December 2015 and in October 2016 – December 2016 during which there was increase of 500 FFS beneficiaries in Puerto Rico for both periods. For this reason, as well as the analysis discussed above of per-capita costs, there was no adjustment applied to 2017 FFS enrollment and claims experience in Puerto Rico to account for Hurricane Maria.

Comment: A large number of commenters expressed concern regarding socio-economic conditions in Puerto Rico, citing beneficiary migration to the mainland and an exodus of health care providers, amid hurricane recovery efforts. Commenters noted the FFS expenditure data in Puerto Rico and expressed concern regarding payment disparity between Puerto Rico and the mainland. Commenters urged CMS to explore all potential options for reforms to stabilize the marketplace, improve the health care infrastructure, and achieve greater parity with the FFS rates on the mainland.

Commenters provided suggestions for additional rate adjustments that CMS should consider for Puerto Rico including establishing an AGA floor/proxy (e.g., apply an AGA of 0.70 or apply a nationwide average AGA) or applying a hold harmless minimum benchmark. One commenter cited actions taken by CMS for the Medicare FFS program including that CMS used a national average Geographic Practice Cost Index (GPCI) as a proxy in the Physician Fee Schedule for Territories, and CMS adjusted regulations to establish a floor in the wage index factor used for dialysis payments under Medicare FFS. Commenters expressed concern that the FFS data used to set the MA rates for Puerto Rico are not representative of the population to which rates are applied.

Response: We appreciate the concerns and recommendations commenters have raised regarding Puerto Rico. We will continue to analyze these issues and consider whether any refinements to the methodology may be warranted in future years. As discussed in the 2017 Advance Notice, the law requires that Medicare Advantage benchmarks be based on a county's average Medicare FFS per-capita cost, and there is no evidence that FFS costs in Puerto Rico are higher than the costs observed in the FFS claims data, and thus no basis for overhauling Puerto's Rico's Medicare Advantage benchmarks. As we stated in the 2017 and 2018 Rate Announcements, we believe that the FFS data in Puerto Rico is sufficient for establishing accurate MA benchmarks.

Section D. ESRD Rates

Comment: A large number of commenters requested that we begin studying methodologies to improve the accuracy of the ESRD benchmarks to improve payment adequacy, given the expectation for increased ESRD enrollment in MA beginning in contract year 2021 as a result of the 21st Century Cures Act (Pub. L. 114-255), which allows individuals with ESRD to be eligible

for MA[1]. One commenter expressed concern for potential disruption in the market. Several commenters expressed concern that the ESRD benchmarks are not representative of the costs for ESRD beneficiaries in MA, resulting in underpayment. One commenter indicated that inadequate ESRD rates could result in an increase in premiums or a decrease in benefits for all enrollees. Two commenters expressed concern regarding ensuring that ESRD related costs are accurately represented in the ratebook. One commenter encouraged CMS to exercise its authority to adjust the ESRD rates to more accurately reflect costs.

One commenter cited volatility in the ESRD growth rates, and expressed concern regarding accurately estimating ESRD payment. Another commenter encouraged CMS to study the year-over-year volatility of the ESRD rates, and suggested that CMS consider using six years of historical ESRD data to reduce fluctuations.

One commenter recommended that CMS take steps to ensure that MA plans are adequately paid for ESRD Dialysis beneficiaries given differences in benefit requirements between Medicare FFS and MA, such as adjusting MA benchmarks for ESRD Dialysis beneficiaries to reflect the impact of maximum out-of-pocket (MOOP) cost requirements in MA.

Response: We appreciate the concerns commenters have raised. We will continue to analyze these issues and consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years.

Comment: Commenters provided the following suggestions for revisions to ESRD benchmarks and payment, citing expected increases in ESRD enrollment in MA starting in 2021 from the implementation of the 21st Century Cures Act. Two commenters requested that CMS study the development of ESRD rates on a smaller geographic basis to better reflect cost differences between urban and rural areas, such as developing ESRD rates by county or Metropolitan Statistical Area with the use of ESRD credibility factors and statewide manual rates.

Two commenters indicated that Quality Bonus Payments should be applied to ESRD rates, with a separate ESRD benchmark cap, to allow for a better transition of increased enrollment of ESRD beneficiaries into MA plans.

One commenter expressed concern regarding the large differential between the ESRD dialysis rate and the post-transplant rate, such that MA plans may be incentivized to maintain ESRD enrollees on dialysis (rather than arranging for transplantation). The commenter suggested that the ESRD dialysis rate could be subdivided between ESRD-eligible and Aged/Disabled-eligible beneficiaries, or by age decile, or by the Estimated Post Transplant Survival (EPTS) scores, such that MA plans would not be incentivized to "cherry pick" younger and healthier ESRD-eligible

[1] Previously, only individuals who developed ESRD while already enrolled in an MA plan could be considered eligible for MA.

beneficiaries and retain them on dialysis. The commenter also suggested that CMS modify the rate methodology such that similar payments are provided for patients on dialysis and those who have been transplanted for some defined post-transplant period.

Response: We appreciate the feedback submitted by commenters regarding this issue. We will continue to analyze these issues and consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years. Further, we believe that significant changes to the current methodology, especially of the magnitude described by the commenters, should be fully examined and included in the Advance Notice and subject to notice and comment.

Comment: One commenter recommended that CMS work with antitrust regulators to take steps to address the highly-concentrated nature of the dialysis provider market, citing market consolidations and the small number of organizations operating most of the dialysis stations in the United States. The commenter indicated that such high concentration in this market raises concerns about the consolidation's impact on competition, quality of care, innovation, and costs. Another commenter indicated that the concentration of dialysis providers and network adequacy requirements affect a plan's ability to negotiate reasonable reimbursement for dialysis services.

Response: We appreciate the feedback submitted by commenters regarding this issue.

Comment: One commenter indicated that it is important that MAOs and other stakeholders have the opportunity to evaluate data associated with ESRD beneficiaries in Medicare FFS to understand the demographic and clinical characteristics of the population, as well as the financial implications of enrollment of this population into MA. The commenter requested that the Master Beneficiary Summary File (MBSF) be revised to include ESRD status (Dialysis, Graft 1, Graft 2, Post-Graft 1 and Post-Graft 2), on both the 100 percent MBSF File and the 5 percent sample Limited Data Set (LDS) file.

Response: We appreciate the feedback submitted by commenters regarding this issue. We will consider sharing this information with stakeholders.

Comment: Two commenters expressed appreciation for CMS's work to update ESRD payment methodologies and CMS's efforts to improve transparency, and also requested additional opportunities and timely information to better understand the development of payment components, such as changes in FFS payment systems. The commenters expressed concern that the ESRD benchmarks need to accurately capture and incorporate FFS expenditures in a timely manner for new benefits and services, citing an expanded availability of the ESRD Prospective Payment System (PPS) add-on payment to incentivize the development of innovative drug therapies.

Response: The CY 2020 dialysis-only ESRD USPCC reflects our best estimate of the national per-capita cost, including changes to the ESRD bundled payments made in final rules published

before issuance of the Advance Notice. The repricing adjustments to FFS costs, which support the average geographic adjustments (AGAs), reflect changes in the wage index or GPCIs from the experience year to, as applicable, CY 2019 or FY 2019. The county-level repricing adjustments do not reflect updates to the composition of the bundle, such as changes in the covered drugs. The actual cost of the bundle changes will be reflected in the historical FFS experience used in the development of the AGAs.

Comment: Two commenters requested additional transparency regarding the approach to account for the impact of alternative care delivery models on the ESRD rate setting process. The commenters expressed concern that these programs, such as the ESRD Seamless Care Organization (ESCO) model, have a lag time in determining savings and losses that could result in understated FFS ESRD costs. One of the commenters suggested that CMS could extrapolate performance year 1 data to estimate the 2017 shared savings payments for the ESCO model.

Response: The expected net aggregate performance payments of alternative care delivery models are reflected in the national USPCC calculations. Further, similar to the methodology used for non-ESRD FFS cost tabulations, we only include in historical claims performance payments that have been reconciled with providers and/or sponsoring organizations, since the adjustments can vary geographically.

Comment: One commenter requested clarification regarding the data cohort used to establish ESRD dialysis rates paid to MA plans, asking whether dialysis rates are computed using cost data for both ESRD-eligible and Aged/Disabled-Eligible beneficiaries, or based on cost data for Aged/Disabled-eligible beneficiaries only.

Response: The ESRD dialysis rates paid to MA plans are based on FFS experience for Medicare beneficiaries in ESRD dialysis status.

Comment: One commenter noted that, under the 21st Century Cures Act, organ acquisition costs are to be excluded from the MA rate methodology and paid under FFS Medicare in 2021. The commenter requested that organ acquisition costs be treated as a pass through cost in 2020, preceding implementation of the 21st Century Cures Act organ acquisition cost pass-through methodology.

Response: Section 17006(b) of the 21st Century Cures Act amends sections 1853(k)(1) and 1853(n)(2)(E) of the Social Security Act to exclude the costs for kidney acquisitions from MA capitation rates and benchmarks beginning with 2021. Section 17006(c) amends sections 1852(a)(1)(B)(i) and 1851(i) of the Act to provide that, starting in 2021, payment for MA enrollees' kidney acquisition costs will be made under Medicare FFS. For setting payments to MA plans in 2020, we continue to include kidney acquisition costs in MA capitation rates and benchmarks.

Comment: Several commenters cited recent decreases in the ESRD rates in Puerto Rico, which they indicated results in funding inadequacies and provider access issues for ESRD beneficiaries in Puerto Rico. One commenter expressed concern regarding the level of ESRD rates in Puerto Rico compared to the nationwide average. Commenters provided suggestions for rate adjustments that we should consider, including establishing an AGA floor (e.g., apply an AGA of 0.70), using a proxy benchmark (e.g., use the rates of US Virgin Islands), and adjusting rates for the increase of the Medicare FFS wage index floor for dialysis payments in Puerto Rico.

Response: We appreciate the concerns commenters have raised regarding ESRD rates in Puerto Rico. We will continue to analyze these issues and consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the methodology may be warranted in future years. As we stated in the 2018 Rate Announcement, we believe that the FFS data in Puerto Rico is sufficient for establishing accurate MA rates as well as consistent with the statutory requirements.

Section E. MA Employer Group Waiver Plans

The bid-to-benchmark ratios applied in calculating 2020 MA EGWP Payment Rates are:

Applicable Percentage	Bid to Benchmark Ratio
0.95	84.7%
1	86.6%
1.075	86.1%
1.15	86.5%

The steps in the payment methodology for 2020, as well as the applicable rules, are being finalized as proposed in the 2020 Advance Notice.

Comment: The majority of commenters expressed support for the proposal to continue the 2019 payment methodology that differentiates between PPO and HMO EGWP and individual market plans and expressed a desire to maintain stability in the EGWP market.

Response: We appreciate the support.

Comment: The majority of commenters expressed appreciation and support for the proposal to permit EGWPs to buy-down the Part B premium for their enrollees.

Response: We appreciate the support.

Comment: A couple of commenters recommended that CMS publish preliminary bid-to-benchmark ratios in the Advance Notice using prior year bids using either December or the most current enrollment available.

Response: As described in the Advance Notice, in order to have the most accurate data incorporated into the payment methodology, the bid-to-benchmark ratios used for 2020 payment have been calculated using February 2019 enrollment, which was not available at the time Part II of the 2020 Advance Notice was published. We finalized use of the February enrollment in calculating the bid-to-benchmark ratio in the CY2019 Rate Announcement in order to have the most accurate data available incorporated into the payment methodology for the bid-to-benchmark ratios used for payment. We are concerned that if we were to use either December or January enrollment as a proxy to calculate preliminary bid-to-benchmark ratios in the Advance Notice, they may not be representative of the final bid-to-benchmark ratios using February enrollment ultimately used in the calculation, given the enrollment trends in both the individual and employer markets that we have seen over the past several years. Notwithstanding the foregoing, we appreciate these commenters concerns and will consider whether publishing additional preliminary information in future years would be helpful to have a more robust understanding of this policy.

Comment: A few commenters recommended refinements to the proposed implementation of the Part B premium buy-down. One commenter recommended that CMS consider establishing a segment ID in the plan benefit package (PBP) to facilitate additional flexibility for Part B buy-downs for enrollees in the same EGWP PBP, while others requested that CMS consider providing greater flexibility in general for the amount populated in the PBP so it can either reflect a fixed dollar, a percentage of the standard Monthly Part B premium, or not limited by a designated value. One commenter sought confirmation that the proposal to buy-down the Part B premium applies to all MA EGWPs, including those that have a plan premium.

Response: As described in the 2020 Advance Notice, when an individual market MAO submits a bid to CMS, the MAO is permitted to use MA rebates to buy-down a portion of the Part B premiums for its enrollees by identifying the buy-down amount in the bid pricing tool. CMS then retains the rebate amount specified by the MAO and coordinates directly with the Social Security Administration (SSA) to ensure that each beneficiary's Part B premium is appropriately calculated and withheld from the beneficiary's Social Security check or billed to the beneficiary. For 2020, MA EGWPs (including those that have a plan premium) are permitted to buy down Part B premiums for their enrollees, using a portion of the Part C payment. As also noted in the 2020 Advance Notice, while rebate dollars will continue to not be specifically identifiable, we believe that since the amount paid to MA EGWPs represents the equivalent of a basic benefit capitation and rebate amount that would similarly be paid to an individual market MAO, permitting MA EGWPs to use a portion of the Part C payment to buy down the Part B premium is an appropriate use of these funds in the course of offering an MA benefit. Implementing this payment methodology should not unnecessarily restrict an MA EGWP's ability to offer this benefit and should instead be in equity with individual market plans in this regard. Implementing the waiver as described also facilitates the communication of this information from CMS to SSA by maintaining a similar operational structure to that which exists for individual market MAOs.

Under the policy being finalized, MA EGWPs will be subject to the same maximum CY 2020 Part B buy-down amount as non-EGWP plans. That is, EGWPs will be permitted to only buy down the Part B premium up to the maximum amount displayed in the CY 2020 MA Bid Pricing Tool Worksheet 6[2], i.e., the same maximum amount applicable to non-EGWP plans. Additionally, similar to non-EGWP plans, the Part B buy-down amount cannot vary among beneficiaries under a plan. The Part B buy-down amount applies to every beneficiary under the plan ID. Therefore, if an EGWP would like to reduce the Part B premium for one employer group under the plan ID by $5 and reduce the Part B premium for another employer group by $10, then two separate EGWP plan IDs would need to be established and utilized. Implementing the waiver as described facilitates the communication of this information from CMS to SSA by maintaining a similar operational structure to that which exists for individual market MAOs, and puts MA EGWPs on equal footing with individual market plans. Notwithstanding the foregoing, we appreciate the considered thoughts on this issue, and will continue to analyze and explore suggestions for refinements to this policy in the future.

Comment: A couple of commenters opposed continuing to waive Part C bidding requirements for sponsors of Part C EGWPs, asserting that we should reinstate the annual Part C EGWP bidding process that existed prior to 2017.

Response: As we have stated previously, we continue to believe that the policy of allowing MAOs to submit composite bids and benefit packages is not an appropriate methodology for payment given the lack of competition and transparency associated with EGWP bids received prior to 2017. As detailed in prior years, the alternative to the composite bids submitted prior to 2017 would require significantly more information to be collected, submitted, and reviewed by CMS. Moreover, it would require reverting to the statutory and regulatory requirement of requiring EGWP sponsors to submit to CMS for review and approval benefit packages and bids for each of their employer plans. We have consistently concluded that the administrative burden for not just the government, but for MAOs and employers, of such an approach would substantially hinder the offering of these plans as MAOs would have to commit to specific plan benefit packages at the time of the bid, the flexibility to modify benefits and customize plan offerings for employers would be significantly limited or eliminated entirely as compared to the flexibility provided under either the composite bid waiver or the current payment policy, and changes after bid submission would be more difficult, or perhaps impermissible. We continue to believe that the policy being finalized for 2020 has the correct balance of facilitating the offering of these valuable products by reducing significant burden and increasing payment accuracy for these offerings.

Comment: One commenter recommended a modification to the formula used to calculate the bid-to-benchmark ratio, suggesting that there should be separate ratios used for each plan type

[2] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions.html

instead of weighting them to result in a single ratio per quartile, resulting in separate payment rates for HMO EGWPs and PPO EGWPs.

Response: Introducing additional complexities into the already complex formula in the final Rate Announcement would contribute to a lack of transparency and possible inconsistencies in the year-to-year payment rates. We believe that any significant changes to the current methodology should be included in the Advance Notice and subject to notice and comment. We appreciate this considered thought on this issue, and will continue to analyze and explore this suggestion, as well as other options, for incorporating refinements to this payment methodology as needed in the future.

Section F. CMS-HCC Risk Adjustment Model for CY 2020

Comment: Most commenters expressed support for the extensive research and development CMS has undertaken to improve risk adjustment and supported the inclusion of variables that took into account the number of conditions a beneficiary may have. A majority of commenters recommended that CMS finalize the Alternative Payment Condition Count (APCC) Model that incorporates additional HCCs for pressure ulcers and dementia. Many commenters stated that the APCC model is more accurate than the proposed Payment Condition Count (PCC) model, which will lead to more appropriate reimbursement, especially for plans that serve the sickest beneficiaries, and, in turn, will improve access to care. Furthermore, these commenters strongly supported the inclusion of additional HCCs for dementia and pressure ulcers. They stated that including these HCCs would result in a more accurate prediction for this medically complex, high cost population. Many other commenters preferred that the proposed PCC model be implemented as opposed to the APCC model. They cited the improved accuracy of the PCC model relative to the 2019 model, the increased operational burden of implementing a model that was not previously proposed, and the need to minimize changes to risk adjustment each year. One commenter agreed with the constraint on the two dementia HCCs in the APCC model, but requested more information on why the constraint is necessary. Several commenters disagreed that CMS should constrain the coefficients for the two dementia HCCs in the APCC model, stating that the two HCCs represented conditions that are distinct; both clinically and by cost. Two commenters cited concern over the specificity of the dementia HCCs, and one noted CMS's previous decision to exclude dementia HCCs because of the degree of specificity and potential payment inaccuracies if dementia is reported more in Medicare Advantage relative to FFS Medicare.

Response: We thank the commenters for their support. For CY 2020 we are finalizing the Alternative Payment Condition Count (APCC) model for the blended risk score calculation. This model includes additional HCCs for dementia and pressure ulcers as well as variables that take into account the number of conditions a beneficiary may have, and makes an adjustment as the number of conditions increase, which is a requirement of the 21st Century Cures Act. As stated in Part I of the 2020 Advance Notice, we interpreted the statute's directive to improve risk

adjustment to mean improving the accuracy of the cost predicted by the risk adjustment model across subgroups of beneficiaries in the program. By decile of predicted risk, our standard measure of model accuracy, the APCC model is more accurate than the 2019 CMS-HCC model — the predictive ratio is closer to 1.0 for nearly all deciles in each segment — and in addition, the APCC model is more accurate than the PCC model for a majority of deciles in each model segment and by count of chronic condition.

We agree with commenters that including the additional HCCs for dementia and pressure ulcers will improve prediction for beneficiaries with those conditions, who as a group are a medically complex, high cost population. While we acknowledge the concern related to the specificity of the dementia HCCs, and the potential effect this could have on payment, as noted in Part I of the 2020 Advance Notice we think the concern is sufficiently addressed by constraining the two dementia HCCs so that they have the same relative value. We believe that by applying the constraint we have appropriately balanced the inclusion of this condition in the model with the effect that this clinical discretion could have on payment and the need to accurately predict cost for a medically complex, high cost population.

Comment: Many commenters stated that the proposed PCC model and APCC model could have unintended consequences because, under both of these models, risk scores decrease for some beneficiaries with three to six conditions, or who are assigned to the full dual disabled segment, and risk scores increase for some beneficiaries without HCCs. Several of these commenters suggested that because of the impact on risk scores neither the PCC model nor the APCC model met the intent of the 21st Century Cures Act.

Response: CMS's standard measure of accuracy for the risk adjustment model is the predictive ratio. As can be seen in tables 5-36 through 5-40 of the December 2018 Report to Congress on risk adjustment in the Medicare Advantage program, the 2019 CMS-HCC model's predictive ratio by count of payment conditions is over 1.0 (predicted cost is higher than actual cost) for beneficiaries with between 1 and 6 payment HCCs.[3] Including a count of payment conditions in the model (most of which are chronic conditions) improves the accuracy of prediction by count of payment conditions (the predictive ratio is closer to 1.0). Thus, since the 2019 CMS-HCC model was over-predicting cost for beneficiaries with between 1 and 6 payment conditions, a more accurate model will appropriately reduce the predicted cost for these beneficiaries. Furthermore, because risk scores can change between model calibrations for reasons other than changes in the model specification, such as differences between the model calibration sample and the population for which risk scores are calculated, we do not consider risk score changes alone a valid means of assessing the accuracy of the model.

[3] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/ReportToCongress.html

Comment: Many commenters identified changes to the model that they thought would either improve the model's accuracy or better meet their interpretation of the intentions of the 21st Century Cures Act. Some of the recommended changes include: separately adjusting for the diagnoses in the drug and alcohol "poisoning" group that were added to HCC 55, calibrating the model using ICD-10 diagnosis codes, accounting for activities of daily living in the model, using two years of diagnostic data to calibrate the model, taking into account social determinants of health, implementing a mortality adjustment, calibrating the model with a mix of prospective and concurrent diagnoses, counting all conditions rather than payment conditions, and adding more clinically specific interaction terms instead of count variables.

Response: We appreciate the detailed suggestions to improve the accuracy of the risk adjustment model. As previously noted, the 21st Century Cures Act requires that a specific adjustment for the number of conditions that a beneficiary has be included in the model and that this adjustment be fully phased-in by 2022. While there are other changes that may improve the accuracy of a risk adjustment model with count variables for certain groups of beneficiaries, for 2020 we must implement one of the two models discussed in Part I of the 2020 Advance Notice that makes an adjustment for the number of conditions a beneficiary has in order to meet the requirements of the statute.

We will take into consideration the commenters' suggestions for improving the model in future recalibrations. We would also like to note that, because the 21st Century Cures Act requires that a model that meets the requirements of section 1853(a)(1)(I)(i) of the Social Security Act be fully phased-in by 2022, we believe that we must phase in a model including at least the count variables and the HCCs in the APCC model over the period from 2020 to 2022, after which we may consider additional improvements to the count variables and condition categories or variables included in the model. This will also promote payment stability as we phase in this new model. As discussed in the 2018 Report to Congress, calibrating a model with ICD-10 diagnoses will be one of our primary considerations moving forward.

Comment: Most commenters supported CMS's proposal to phase in the requirements for the 21st Century Cures Act by implementing a model in 2020 that includes condition count variables by blending 50 percent of the risk score calculated from the new model with 50 percent of the risk score calculated from the old model. Several commenters suggested that CMS phase in the model under differing timeframes, such as 33 percent in 2020, 67 percent in 2021, and 100 percent in 2022, with some suggesting that CMS phase in the model over a longer period of time despite the statutory direction. A few commenters requested clarification on the source of diagnosis data that would be used for risk score calculation if CMS finalized the APCC model.

Response: We appreciate the support for phasing in a model with count variables. For payments in 2020, we are finalizing the phase-in of the APCC model as proposed: 50 percent of the APCC model risk score will be blended with 50 percent of the 2017 CMS-HCC model risk score. Diagnoses from encounter data records, FFS claims, and RAPS inpatient records will be

included in the calculation of the APCC model risk score. Diagnoses from all RAPS records and FFS claims will be included in the calculation of the 2017 CMS-HCC model risk score.

The 21st Century Cures Act requires that any changes to risk adjusted payments under section 1853(a)(1)(C)(i) resulting from the implementation of section 1853(a)(1)(I) must be phased in over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years. We began implementing the 21st Century Cures Act requirements in 2019 with a model that included additional conditions for chronic kidney disease, mental health, and substance use disorder. The implementation of a model with condition count variables in 2020 is a continuation of the policy first proposed in the 2019 Advance Notice. Thus, we believe stakeholders have had sufficient time to evaluate the impacts of the new specification and feel it is appropriate to continue with the phase-in for 2020 as proposed. We will continue to evaluate the phase-in schedule and determine the appropriate blend percentage in future years.

Comment: Some commenters suggested that CMS was not transparent enough and did not provide sufficient details regarding the PCC or APCC model's development or the other model specifications considered prior to proposing the PCC model. Some of these commenters also requested that CMS work with stakeholders to design and develop a model for use in future payment years.

Response: In response to comments on the 2019 Advance Notice that requested additional information and time for consideration of the new model, we delayed implementation of a model that took into account the number of conditions a beneficiary may have and provided stakeholders with additional time to review the proposed model and assess the impacts. In addition, we provided additional information that would allow stakeholders to replicate CMS's work and propose alternatives if warranted. We provided the ICD-9 diagnosis to HCC mappings for all HCCs (including the dementia and pressure ulcer HCCs included in the APCC model), software for the proposed PCC model and the All Condition Count (ACC) model discussed in the 2019 Advance Notice, conducted a webinar discussing our research to develop the proposed models, and published slides from the webinar on CMS research and findings on the CMS website. In the webinar slides, CMS noted the variations of models we considered when developing the PCC model and their performance relative to the model we proposed. While we provided additional time and information, CMS did not receive comments on an alternative specification that met the requirements of the 21st Century Cures Act and improved the accuracy of the model overall.

We are committed to improving the risk adjustment model, transparently and with input from all interested parties. Stakeholders may use the information provided by CMS to test alternative specifications and submit those recommendations. We will consider additional ways in which we can engage with stakeholders as we consider changes to the CMS-HCC risk adjustment model for future years.

Comment: Several commenters requested that CMS clarify why some HCCs, such as HCC 115 (Pneumococcal Pneumonia, Empyema, and Lung Abscess), HCC 76 (Muscular Dystrophy), and HCC 74 (Cerebral Palsy) are constrained to zero in some segments in the PCC model and not constrained in the 2017 CMS-HCC model. Some commenters requested more information on why the count of conditions did not start at two conditions. Another commenter asked for clarification on whether the proposed model only counted chronic conditions and how MAOs should identify chronic conditions.

Response: Individual HCC and count variable coefficients are influenced by a number of factors, such as the prevalence rate of the HCC or count variable in the population used to calibrate the risk adjustment model, and the prevalence rate of associated HCCs or count variables. As explained in the CY 2020 Advance Notice Part I, HCCs are constrained to zero if the coefficient is negative, and count variables are constrained to zero if the coefficient is negative or the count variables are statistically insignificant. We started the count of conditions in each segment at the number of conditions that resulted in a positive and statistically significant estimate. While a model with negative coefficients would have produced reliable estimates, a long standing principle of the risk adjustment model is that plans should not be penalized for submitting additional diagnostic information. Implementing a model with negative coefficients for HCCs or the count variables would have, in some cases, reduced risk scores if an additional HCC were submitted.

When the data years and model specifications change the coefficients for some HCCs that are less prevalent can become negative. The data years for the 2017 CMS-HCC model versus the PCC and APCC models differ. The 2017 CMS-HCC model was calibrated with 2013 diagnoses and 2014 costs, while the PCC and APCC models were calibrated based on 2014 diagnoses and 2015 costs. In addition, the specification is different between the 2017 CMS-HCC model and the PCC and APCC models. The PCC and APCC models have more conditions and include additional count variables for the number of conditions a beneficiary may have. We found that HCC 74's coefficient is frequently affected by changes in associated paralysis HCCs, especially in the segments where the count of HCCs starts higher, and that HCC 76 in the partial dual aged segment and HCC 115 in disabled segments have small sample sizes. In reviewing the HCCs affected by the constraints, we identified two HCCs (HCC 115 and HCC 167) that were erroneously constrained to zero in the non-dual aged segment of the APCC model. The corrected coefficients for the non-dual aged segment of the APCC model are available in Attachment VI.

The count variables in the APCC model count the 86 conditions (HCCs) that are included in that model for payment. A beneficiary is credited with having an HCC if any diagnosis that maps to one of the HCCs in the model (even if that HCC is constrained to zero) is submitted to CMS. MAOs are not required to identify which conditions are chronic conditions when submitting diagnoses for payment. We identified which conditions in the CMS-HCC model were chronic conditions for research purposes only and do not use that concept in identifying or distinguishing

among HCCs used in the model. For information on which conditions we classified as chronic in our research, please refer to section 3.1.2 of the 2018 Report to Congress.[4]

Section G. ESRD Risk Adjustment Model for CY 2020

Comment: While many commenters acknowledged the need to recalibrate the ESRD model, particularly in light of the 21st Century Cures Act permitting ESRD enrollment in MA plans in 2021, they expressed concern about the model's accuracy and that the proposed model, in combination with other updates, such as the ESRD normalization factor, will result in a reduction in plan payments. One commenter was concerned that the analysis of the recalibrated ESRD model in the 2018 Report to Congress is based on predicted, not actual costs, and may not adequately predict relative costs for the ESRD population.

Response: We appreciate the comments and acknowledge the commenters' concerns. For 2020, we will fully implement the updated ESRD risk adjustment model as proposed in the 2020 Advance Notice Part II.

Predictive ratios show the extent to which subgroups predicted to have certain levels of expenditures actually have those levels on average. Given that the objective of the risk adjustment model is to predict the risk of groups of beneficiaries, and is not designed to predict costs at the individual beneficiary level, predictive ratios were not calculated with actual costs. Predictive ratios grouped by actual costs are not meaningful evaluation measures because predicting future medical spending using a model to be used in payment can never exactly predict costs at an individual level. Therefore, CMS uses predictive ratios for groups of beneficiaries based on their predicted expenditures as the measure of model accuracy in predicting relative risk.

Comment: In the 2020 Advance Notice Part II, CMS proposed adjusting the coefficients for the dialysis new enrollee segment to address the over-prediction of costs for this segment. Several commenters expressed concern about this dialysis new enrollee adjustment and disagreed with CMS's approach to adjusting the coefficients for this segment. The commenters requested that CMS either reassess the dialysis new enrollee adjustment or, at a minimum, not apply the adjustment for 2020. In response to CMS's statement that "the population of true new enrollees receiving dialysis is too small to reliably estimate a model," one commenter believed that this contradicts existing CMS policy on ESRD claims credibility presented in the "ESRD Claims Credibility Guideline" memo effective April 10, 2015, issued by the CMS Office of the Actuary (OACT). The commenter felt that it was unnecessary to augment the sample size by including dialysis continuing enrollees and believed that cost patterns for these enrollees in years 1 through 3 differ significantly from dialysis new enrollees. Furthermore, the commenter noted the high number of hospitalizations for the first year of ESRD to support their position that dialysis new

[4] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/ReportToCongress.html

enrollees would cost more than continuing enrollees. Another commenter indicated the belief that many of the frailest patients on dialysis die within the first year of treatment, which leads to increased costs to address serious health conditions and subsequently means the frailest and costly patients would not be in the sample of patients continuing dialysis in years 2 and 3. A few commenters noted that if CMS maintains that a larger dialysis new enrollee sample is necessary, they urged CMS to consider other options, such as multi-year cohorts or multiple years of new dialysis patient data, to achieve a sample that better reflects costs for this segment. One commenter noted their belief that postponing the proposed reduction would not impact the ESRD dialysis normalization factor, given that CMS stated that it applied the proposed reduction to each of the historical risk scores used to calculate the FFS ESRD risk score trend.

Response: We appreciate comments suggesting possible alternative ways to calibrate the dialysis new enrollee segment of the model. Since the new enrollee segment of the ESRD dialysis risk adjustment model distinguishes predicted costs by a set of demographic attributes (age, sex, Medicaid status, and Originally Disabled status), it is necessary to have a large enough model sample to achieve sufficient sample sizes for each variable in order to generate coefficients for each variable in the model. For example, when using 4,000 member months, none of the age-sex variables for ages 70 and older would individually have sufficient sample sizes in our model to estimate coefficients using only data from dialysis new enrollees. Thus, the proposed ESRD dialysis new enrollee model segment for 2020 is calibrated using a combined modeling sample of dialysis new enrollees and continuing enrollees who have been on dialysis for 3 years or less.

As a reminder, new enrollees are those who have fewer than 12 months of Part B in the data collection period; new enrollees include beneficiaries who have been on dialysis for more than 12 months, but are not enrolled in Part B for part or all of the data collection period. Continuing enrollees are those who have 12 months of Part B in the data collection year; continuing enrollees include beneficiaries who are within the first 12 months of dialysis. For example, a Medicare beneficiary who is entitled to Part A and enrolled in Part B for 2 years before beginning dialysis would be in the continuing enrollee dialysis group. As we described in the Advance Notice, the dialysis new enrollee modeling sample comprised both true new enrollees as well as a supplement of continuing enrollees who have been on dialysis for 3 years or less to increase the sample size for the purpose of establishing coefficients for the new enrollee model. We note that our cost data shows that, within each group in the new enrollee model sample – true new enrollees and supplemental continuing enrollees – those within the first 12 months of dialysis are more expensive than the average for each subgroup.

Further, we want to note that true new enrollees have lower overall costs than the continuing enrollees included in the dialysis new enrollee model sample, indicating that the average cost of the continuing enrollees is increasing the average cost of the entire dialysis new enrollee model sample (i.e., combined true new enrollee and supplemental continuing enrollees) that we used to calibrate the new enrollee model. These higher costs are driven by a large group of beneficiaries

among the continuing enrollees in the new enrollee model sample who are within the first 12 months of dialysis.

We would also like to clarify that the dialysis new enrollee relative factors are applied in payment only to enrollees who do not have 12 months of Part B enrollment in the data collection period. Enrollees who are newly enrolled in an MA plan, but who have 12 months of Part B enrollment in the data collection period, are considered continuing enrollees who would have their risk scores calculated using the continuing enrollee dialysis segment.

The dialysis new enrollee model sample has mean expenditures of $72,243 in our 2015 expenditure year data. In our model recalibration and evaluation, we conducted predictive ratio analyses for true dialysis new enrollees (e.g., those without full year Part B enrollment in the data collection period), excluding the continuing enrollees who were part of the modeling sample. We examined age-sex breakouts for the full set of these true new enrollees, the non-Medicaid subgroup, and the Medicaid subgroup. The predictive ratios consistently showed over-prediction for the true dialysis new enrollees: as we described in the 2018 Report to Congress and the 2020 Advance Notice, the average over-prediction was 14.9 percent. For broad groups of dialysis new enrollees, including the Non-Aged (age<65) and Aged (age 65+) subgroups, the over-prediction ranged from 10 percent (for the Medicaid Aged subgroup) to 20 percent (for the non-Medicaid Non-Aged subgroup). For every age-sex variable (e.g., Males, Age 65-69), the model over predicted the true dialysis new enrollees, ranging from 5 percent to more than 45 percent over-prediction.

We also note that the adjustment for the post-graft new enrollee and institutional segments - that results in increases in the factors for these groups - is a result of the need to use alternate model samples for a similar reason, i.e., because the true post-graft new enrollee and LTI samples are not large enough to generate all the coefficients in the post-graft model for these segments. We believe that we have balanced the need for accurate payment by increasing the factors where there are under-predictions, and reducing the factors where there are over-predictions, due to small sample sizes.

For 2020, we will select diagnoses for the ESRD model calibration using the same approach used to filter diagnoses from encounter data records, as proposed in the 2020 Advance Notice Part II. For the reasons described above, we also will implement the adjustments proposed in the 2020 Advance Notice to the dialysis new enrollee, post-graft new enrollee, and post-graft LTI segments of the model to improve payment accuracy. We will continue to evaluate the ESRD models and potential model calibration methodologies that increase the predictive accuracy of the models.

Comment: A few commenters requested specific modifications to the ESRD model for CY2020. One commenter suggested that CMS develop a concurrent risk adjustment model rather than a simple demographic model for risk adjusting new ESRD beneficiaries to account for the costs of

first-year ESRD MA members. Another commenter expressed concern that even younger ESRD patients who meet transplant eligibility requirements may have severe comorbidities that they believe warrant substantial upward risk adjustment in the post-transplant period. They also stated that additional risk factors, including transplant-related statuses of a Medicare beneficiary, could be taken into account as risk factors to adjust the transplant factors and determine payment for the post-transplant period for beneficiaries who receive transplants. A few commenters also requested that CMS amend how it applies new enrollee factors in the ESRD model by allowing members to be considered full risk for risk score calculations if an HCC is identified during the calendar year (and if no HCCs are identified, a new enrollee factor would be applied).

Response: We appreciate the comments and recommendations for updates to the ESRD model. We are not implementing these commenters' recommendations for the ESRD model used for risk adjusted payments in CY2020 because we believe that the proposed model, which is calibrated on more recent data, calibrated using diagnoses filtered based on the same approach used to filter encounter data, and includes adjustments to correct for the under-prediction and over-prediction of costs for small subpopulations, will improve risk adjusted payments for beneficiaries with ESRD. As previously noted, we will continue to analyze and consider whether any refinements to the methodology for the ESRD model calibration may be warranted in future years.

Note that new enrollee risk scores are scores that we use when a beneficiary does not have adequate diagnoses in the data collection year to calculate a full risk score (operationalized as having fewer than 12 months of Part B enrollment in the data collection year). Because prior year data is insufficient to predict risk in the payment year for these beneficiaries, we use a combination of demographic factors (age, sex, Medicaid eligibility, and factors related to the original reason for Medicare entitlement) to determine the risk score of a new enrollee.

Comment: One commenter suggested that CMS extend the transplant factor longer than three months, as some patients experience delayed graft function and continue on dialysis after a transplant, such that the dialysis rate would continue until the patient no longer requires dialysis.

Response: We believe that the risk adjustment model and payment for MA enrollees in the month of and two months after transplant are appropriate and decline to make the change suggested by the commenter. CMS calibrated the transplant factors by including FFS expenditures for the transplant and physician and other services rendered for the hospital stay and the two months after discharge. Therefore, the transplant factors would include the cost of dialysis that occurred during the hospital stay.

Transplant factors are estimated for the month of transplant and the following two months after a transplant. To accommodate the high one-time cost of a transplant, CMS makes payments over three months to cover the transplant and immediate subsequent services. The first month's factor is the largest, as that is the month within which the transplant takes place, while the factors for

months 2 and 3 are smaller for post-transplant recovery. Most of the costs of a transplant accrue in the month of the transplant and the ESRD transplant factors account for this fact. By paying the majority of the cost in the month of transplant, CMS is ensuring that MA Organizations are not disadvantaged if the enrollee dies in the month of transplant.

Comment: A few commenters generally noted their belief that MA Organizations that serve ESRD patients have experienced significant swings in payment rates over the last several years and requested that CMS take steps to improve ESRD payment adequacy and provide year-over-year stability for the ESRD population. Several commenters requested that CMS engage with stakeholders regarding further revisions to the ESRD model for 2021 and requested that future updates to the ESRD risk adjustment model be communicated under a similar timeline as the CMS-HCC model (i.e., CMS should allow stakeholders at least 60 days to review and submit comments on all risk adjustment model proposals) to give plans enough time to properly analyze any contemplated updates.

A couple of commenters requested additional information related to the ESRD risk adjustment model. For example, one commenter recommended that future reports to Congress include more actionable information to inform improvements to ESRD payment accuracy. Another commenter stated that it is unclear whether and to what extent the proposed ESRD risk adjustment methodology could exacerbate or reduce the differential between the capitation rates paid for ESRD beneficiaries on dialysis and those who have received a transplant; the commenter requested that the final Rate Announcement provide illustrations of the capitation rates that will be payable to MA Organizations for enrollees with similar clinical profiles, depending on whether or not the beneficiary is on dialysis or has received a transplant.

Response: We appreciate the comments. As required by the 21st Century Cures Act, CMS must submit a report to Congress on the CMS-HCC and ESRD models by December 31, 2018 and every 3 years thereafter. We will consider ways that we can engage with stakeholders and share additional information as we continue to develop the ESRD risk adjustment model and in future reports to Congress. Regarding the impact of the proposed ESRD payment methodology for 2020, State dialysis rates as well as the final coefficients for the dialysis and transplant factors are released in the Rate Announcement. In addition, we released plan level risk scores in HPMS on February 12, 2019 under the 2019 ESRD model currently used in payment and the 2020 ESRD model so that plans could assess the impact of the update of the proposed model, including the impact of beneficiaries in different segments of the model (e.g., dialysis versus transplant).

Section H. CMS-HCC Risk Adjustment Model Used for PACE Organizations in CY 2020

Comment: Most commenters generally supported CMS' decision to utilize the 2017 CMS-HCC model for PACE payment in 2020 because it would align the risk adjustment model used for PACE organizations with one of the models used to pay MA plans and create consistent risk

adjustment for the complex care needs of enrollees; however, these commenters also expressed concern that the proposed model excludes dementia and other conditions. A few commenters requested that the Alternative Payment Condition Count (APCC) model, which includes dementia HCCs, be used for PACE enrollees as expeditiously as possible.

Response: We appreciate the support for use of the 2017 CMS-HCC model for PACE payment in 2020, which will be finalized as proposed. We acknowledge concerns from commenters that the 2017 CMS-HCC model does not include the dementia HCCs and the request by some commenters to expeditiously implement the APCC model. The APCC model is calibrated using the same approach to identifying risk adjustment eligible diagnoses as is used to identify diagnoses on encounter data records. As such, the APCC model is intended to calculate risk scores using diagnoses submitted on encounter data records. Since we are not calculating separate encounter and RAPS risk scores for PACE in 2020 we cannot implement the APCC model for PACE at this time. CMS will work closely with PACE organizations to develop further guidance and provide technical assistance with encounter data submissions in anticipation of implementing the APCC model for PACE in the future.

Comment: Most commenters believe that the proposed 2017 CMS-HCC model will have a negative impact on payments, and therefore, commenters requested that PACE center staff be allowed to proactively help PACE enrollees complete the Health Outcomes Survey (HOS) and Modified Health Outcomes Survey (HOS-M) surveys without the enrollees' unsolicited request in order to improve survey response rates. In addition, commenters requested that, for the purposes of calculating payment, CMS assume that all Medicaid eligible beneficiaries enrolled in certain PBPs are full dual eligible and stated that all dual eligible beneficiaries in the PACE program are full dual eligible.

Response: We acknowledge the concerns related to improving the response rates for the HOS and HOS-M survey (the responses from which are used to determine a beneficiary's limitations in activities of daily living that are accounted for in the calculation of a contract's frailty score) for PACE enrollees, especially those enrollees with dementia. However, for the HOS-M, a proxy response will remain under the control of the beneficiary, but PACE staff may check with family or a caregiver to determine if participants with dementia need assistance with the survey.

Furthermore, regarding the determination of dual status for beneficiaries in PACE plans, CMS will use the system of record (reporting from State and Territory Medicaid agencies that are conveyed to CMS via the Medicare Modernization Act (MMA) state files, Point of Sale data, and the Puerto Rico monthly Medicaid file) to determine dual status. This is the same method that is used for all MA enrollees. Furthermore, while all dual eligible beneficiaries enrolled in any particular PACE organization may be full dual eligible, it is not a requirement that they must be full dual eligible. 42 C.F.R. § 460.150(d) states that the eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid beneficiary. A potential PACE enrollee may be, but is not required to be, any or all of the

following: (1) Entitled to Medicare Part A. (2) Enrolled under Medicare Part B. (3) Eligible for Medicaid. Thus, we cannot make assumptions about dual status or include additional sources of data for identifying dual status. Currently, a Medicaid factor is applied to payment for PACE beneficiaries only if there is at least one month of dual status in the data collection period. This means that a beneficiary that becomes dual eligible in the payment year will not have the Medicaid factor applied in payment for that year. With the 2017 CMS-HCC model, as proposed in the CY2020 Advance Notice, dual status is concurrent based on payment month status, therefore status changes in the payment year will be captured. Our data shows that in recent years, a majority (approximately 97%) of the member months for beneficiaries enrolled in PACE organizations were dual status months. Further, retroactively determined dual status for PACE enrollees will be identified and, if needed, retroactive payment adjustments will be applied to account for dual status.

Section I. Frailty Adjustment for PACE Organizations and FIDE SNPs

Comment: A few commenters expressed appreciation for updating the frailty factors and their continued application to FIDE SNPs.

Response: CMS appreciates the support.

Comment: A couple of commenters requested that the timeline for making a determination about FIDE SNP qualification be earlier.

Response: The frailty scores for the upcoming year are calculated using results from the most current HOS/HOS-M survey. To provide frailty scores at an earlier date, we would have to use older survey data for frailty score calculation. Using survey results from the most current HOS/HOS-M enables us to calculate frailty scores for an upcoming payment year that are based on the most recent survey information, and thus are most likely to reflect the average level of frailty for beneficiaries enrolled in the plan in the payment year as measured by limitations in activities of daily living. Further, using older data would pose challenges to new plans whose sponsors would need to wait another year before having a frailty score applied in payment. However, we will continue to consider ways to improve the timing of the frailty calculations in future years.

Comment: One commenter requested that CMS verify the blended frailty scores for FIDE SNPs and specifically address why the frailty factors for beneficiaries with between zero and four limitations in the activities of daily living who are eligible for Medicare and Medicaid are less than the factors for beneficiaries with between zero and four limitations in the activities of daily living who are only eligible for Medicare.

Response: There are two components to the frailty adjustment that is applied in payments to PACE organizations and FIDE SNPs, the frailty factors and the frailty score. The blend applies to the frailty score for FIDE SNPs. Like the blend applied to the risk adjustment models used in

MA payment for 2020, for FIDE SNPs, the frailty score will also be calculated as a blend. The frailty score for FIDE SNPs will be calculated using the data from beneficiaries who respond to the survey; these frailty scores will be calculated by blending the frailty scores calculated using both the frailty factors associated with the APCC risk adjustment model and the frailty factors associated with the 2017 CMS-HCC model. The two frailty scores will then be blended such that 50% of the frailty score calculated from the APCC model frailty factors is summed with 50% of the frailty score calculated from the 2017 CMS-HCC model frailty factors. The blended frailty score will be compared to the PACE level of frailty in the same manner as CY 2019 to determine whether that FIDE SNP has a similar average level of frailty as PACE.

The frailty factors are updated whenever the CMS-HCC model changes, since the frailty factors for a given model can vary and, therefore, the predicted residual costs may be different for each model used in payment. As the commenter noted, some factors for non-dual beneficiaries are greater than the corresponding factors for dual eligible beneficiaries. As in the previous response, this is because the factors predict the residual cost – the difference between the cost predicted by the model and the actual cost. Thus, the factors may be higher or lower depending on the extent to which the cost associated with each category of limitations in the activities of daily living is predicted by the model.

Comment: A couple of commenters provided suggestions to address some of the perceived limitations of the HOS and HOS-M surveys for measuring frailty status and to improve their accuracy for use in developing the frailty factors. Examples of suggested approaches to improve the collection of information on frailty status include ensuring the validity, reliability, and accuracy of the instrument for all beneficiary groups, ensuring sampling methods are robust, and ensuring that the methods do not place unreasonable or undue administrative burden on beneficiaries, providers, or plans.

Response: The Health Outcome Survey has had considerable validation of its ability to accurately capture functional limitations and other health related characteristics. For example, see, “Patients’ self-report of diseases in the Medicare Health Outcomes Survey based on comparisons with linked survey and medical data from the Veterans Health Administration,” (Journal of Ambulatory Care Management, 2008 Apr-Jun; 31(2):161-77) by Dr. Miller Rogers and colleagues. While we understand that surveys can have operational challenges in administration, as noted in prior Rate Announcements (e.g., 2019), we believe that the HOS and HOS-M (a subset of the questions included in the HOS) continue to provide an accurate and representative measurement of frailty at the plan level because they collect ADL-related data in the same manner that we collect it for model calibration (i.e., limitations in activities of daily living collected from written surveys). In addition, they collect data consistently across respondents, such that frailty scores are calculated using data collected in the same manner across plans, thereby allowing survey results to be compared across plans (a requirement for determining whether FIDE SNPs receive a frailty adjustment in payment) and thus resulting in frailty payments that are equitable.

Comment: One commenter suggested that hospice status be considered by CMS in determining residual costs in preparation for the implementation of hospice payment policy in the MA VBID demonstration for 2021.

Response: We thank the commenter for the comment and will consider it in developing payment policy in connection with that model. As MA plans do not cover hospice under current law, no changes will be made to the general MA payment policy.

Comment: Several commenters noted that dementia is not included in the 2017 CMS-HCC model proposed to calculate risk scores for PACE organizations in 2020 and expressed concern that the frailty factors under the 2017 CMS-HCC model are insufficient to account for dementia.

Response: We appreciate the concern, but note that the frailty factors are calibrated to take into account all cost not predicted by the CMS-HCC model (the residual). For beneficiaries with conditions that are not directly incorporated in the model, such as dementia, the associated costs can be predicted by comorbid conditions and demographic factors; to the extent that these costs are not predicted by the model, they are more likely to be reflected in the frailty factors. However, while the costs are included in the calibration, results for individual plans may differ due to differences between the calibration sample and the population enrolled in the plan.

Comment: A few commenters requested that frailty be applied to all Medicare Advantage plans or all MMPs or to D-SNPs that are not FIDE SNPs that also primarily serve populations with complex needs.

Response: By law, CMS must use the same payment methodology for all MA plans, including Special Needs Plans (SNPs), except as explicitly provided for in statute. For example, section 1853(a)(1)(B)(iv) of the Act authorizes CMS to make frailty-adjusted payments to certain dual SNPs – those with fully integrated, capitated contracts with states for Medicaid benefits, including long term care, and which have similar average levels of frailty as the PACE program. Thus, CMS cannot make frailty payments to any SNP that does not meet these criteria without implementing frailty payments program-wide.

CMS has explored ways of calculating a frailty score for each MA plan and found challenges with a number of approaches (see the "Evaluation of the CMS-HCC Risk Adjustment Model," published March 2011, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf). The CMS-HCC model is intended to accurately pay plans with average risk profiles, unlike PACE organizations and qualifying FIDE SNPs that have higher than average risk profiles and are eligible to receive frailty payments. Because the frailty factors are calibrated using the residual of the CMS-HCC model (the difference between the predicted expenditure amounts and the actual expenditure amounts), and frailty scores have an average value of zero, the application of a frailty adjustment to all MA plans would result in some plans receiving a negative frailty adjustment. Finally, frailty adjustments are calculated using survey data gathered from enrollees

of PACE organizations and FIDE SNPs and are calculated at the contract level for PACE organizations and at the plan level for FIDE SNPs; because of the timing of these data collections (as discussed previously in section I), we are concerned that plans would be required to submit their bids prior to the payment year without knowing what their frailty adjustment would be for that year.

Determination of whether the frailty adjustment will be applied to MMPs as part of that demonstration is outside the scope of this Rate Announcement and will be addressed separately.

Comment: A couple of commenters expressed concern regarding the methodology used to determine whether a FIDE SNP is eligible for a frailty adjustment because frailty scores of PACE members (all of whom must meet state requirements for institutional level of care) are compared to frailty scores of FIDE SNP enrollees (not all of whom meet an institutional level of care).

Response: Section 1853(a)(1)(B)(iv) of the Act directs CMS to look at a FIDE SNP's level of frailty in comparison to the average PACE level of frailty in authorizing the application of a frailty adjustment for FIDE SNPs. Thus, we believe that our policy is consistent with the statute. As discussed in previous Advance Notices and Rate Announcements, in order to compare FIDE SNP frailty scores to PACE frailty scores, we first establish a PACE organization range of frailty based upon those PACE organizations with at least 100 respondents to the HOS survey. Once the PACE range is established, those FIDE SNPs that have a frailty score at or above the minimum PACE score will receive a frailty add-on to their qualifying beneficiaries' risk scores. Low enrollment (fewer than 30 respondents to the HOS/HOS-M) or new FIDE SNPs (those who were not eligible to participate in the HOS due to the length of time the plan was in operation) are not able to receive a frailty score.

Section J. Medicare Advantage Coding Pattern Adjustment

Comment: The majority of commenters were pleased that we proposed the statutory minimum and supported our application of the proposed 5.90% for the 2020 coding intensity adjustment.

Response: We appreciate the support of the commenters. We are finalizing the proposed adjustment of 5.90% for 2020.

Comment: A few commenters indicated that coding patterns in MA are heterogeneous and that applying an across-the-board adjustment is inequitable. One commenter indicated that an across-the-board coding pattern adjustment disproportionately penalizes physician organizations. Another commenter suggested a segmented approach to coding pattern adjustments that recognizes different levels of coding intensity among plans, such that a low coding factor is applied to lower coding plans while a larger factor is applied to higher coding plans.

One commenter that supports the concept of transitioning to the use of encounter data to calculate MA plan risk scores suggested that the coding adjustment will no longer be needed when the transition is fully implemented because the data would reflect actual MA experience rather than FFS experience.

Response: CMS appreciates commenters' feedback. We continually develop our understanding of coding trends and make an assessment for each payment year regarding the appropriate adjustment based on specific considerations of both coding trends and other market changes. Section 1853(a)(1)(C)(ii) requires application of an MA coding pattern difference factor to risk scores; we believe that using a uniform adjustment is an appropriate and efficient approach to achieving the requirements of the statute and that the statutory minimum adjustment level provides an equitable approach for 2020.

Comment: One commenter believed that it is fundamentally incorrect to assume any observed coding differentials between the FFS and MA populations are driven by inappropriate coding on the part of MA plans and urged CMS to recognize that higher coding does not necessarily equate to wrong coding.

Response: As we have noted in previous Advance Notices and Rate Announcements, we are not assuming that MA coding is inaccurate in calculating the MA coding pattern difference factor. Rather, as required by statute, we assume that coding is accurate and apply the MA coding pattern difference factor to address differences in coding patterns. By applying this coding pattern difference factor, we are adjusting for the impact on MA risk scores of coding patterns that differ from FFS coding, which is the basis of the CMS-HCC model and the Part C normalization factor.

Comment: A few commenters urged CMS to work with stakeholders to develop the methodology for determining the MA coding adjustment factor.

Response: We appreciate the comments. The statute requires that CMS apply the MA coding pattern adjustment factor to risk scores.

Section K. Normalization Factors

Comment: Most commenters supported a linear methodology for calculating the normalization factor, but many commenters suggested we make an adjustment to how we apply the current methodology for calculating the normalization factor, and a few commenters suggested we make a change to our methodology. Commenters agreed with CMS that the effect on the change in average risk score from implementing ICD-10 would stabilize moving forward, and thought that the proposed methodology resulted in an increase in normalization factor that was artificially high due to the implementation of ICD-10. Commenters provided a number of options for how CMS could adjust for the increasing trend, including adding more years of data to the calculation

of the slope, adjusting the underlying data for the effect of ICD-10, and recalibrating the model with more recent data.

Response: We are finalizing the normalization methodology as proposed. While we appreciate the suggestions to change how we calculate the normalization factors, we believe that the proposed methodology – using a linear approach with 5 years of data – will produce an appropriate estimate of the 2020 average risk score under each model. The goal of the normalization factor is to accurately predict the FFS risk score in the payment year; thereby maintaining an average FFS risk score of 1.0. Updating the normalization factor annually stabilizes payment between model calibrations. In addition, we have consistently used five years of historical data when calculating normalization factors with the linear slope methodology. Using five years of data to calculate the slope provides a smoothing effect. Since 2015, when ICD-10 was first implemented, the FFS risk score has increased by 1.8 percent per year on average. By including two years without ICD-10 diagnoses (2014 and 2015) the average increase in FFS risk score decreases to 1.4 percent per year. While there is inherent uncertainty with any prediction of future values, the five year trend already includes two years that do not exhibit the same increase observed from 2016 to 2018, which provides a smoothing effect in the event the FFS risk score increase slows down in the future.

As stated in the Advance Notice, our analysis indicates there are multiple factors contributing to the increase in average FFS risk score from 2015 to 2018, and of those, the implementation of ICD-10 is one that we expect to stabilize moving forward. However, as we also noted, we do not expect the average Original FFS Medicare risk score to decrease. Instead, we believe that other factors, such as more complete reporting of diagnosis codes as a result of the changing incentives due to the implementation of alternative payment models in Original FFS Medicare and a changing case-mix, including demographics, will continue to put upward pressure on the FFS risk score.

Comment: A number of commenters requested that CMS provide more information on the methodology for developing the normalization factor and asked for more transparency regarding why more recent years' risk scores were increasing. Many commenters specifically requested that we provide more detail on the factors driving the increase, including quantifying the impact of demographics, reported health status of the Original FFS Medicare population, and ICD-10 implementation. Several commenters made suggestions related to 2021, including that CMS analyze the FFS normalization factors in relation to the FFS growth rate, and that CMS recalibrate the model with ICD-10 diagnoses.

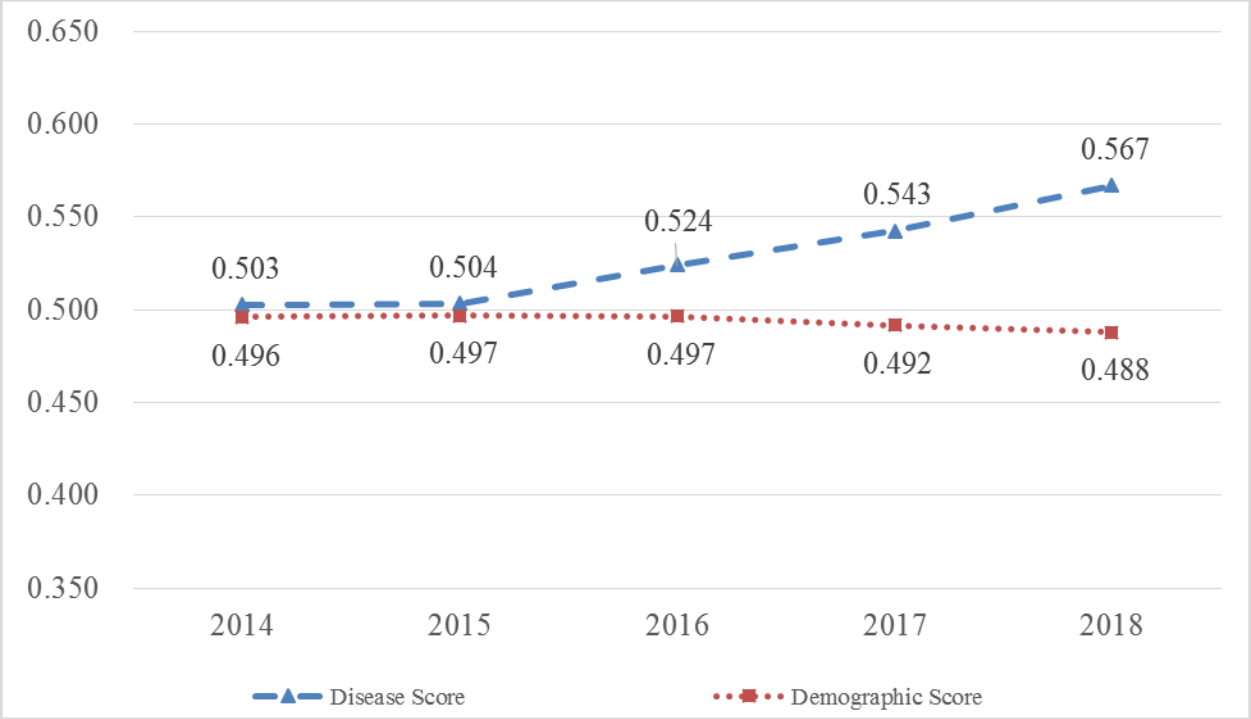
Response: The normalization factor for each model is an estimate of the average Original Medicare (FFS) risk score in the payment year. We project the normalization factor from a set of annual average FFS risk scores. For Part C, PACE, and ESRD post-graft, the historical risk score for each year is calculated as the average risk score for all beneficiaries in FFS who are entitled to Part A, enrolled in Part B, and not in ESRD or hospice status. We then compute the trend over

five years by calculating the slope in risk scores from the beginning to the end of the historical period, then compounding the average change from the denominator year (1.0) to the payment year. In determining the ESRD dialysis and RxHCC normalization factor, we follow the same method, except we use the population of beneficiaries in dialysis status for the ESRD dialysis model normalization factor, and beneficiaries who are enrolled in MA-PD or PDP Part D plans for the RxHCC model normalization factor.

Under any model, the average risk score can change from year to year for a number of reasons, including changes in demographics, disease prevalence, coding practices, and utilization. Figure III-1 shows the trend in risk score by disease and demographic variables for the 2017 CMS-HCC model.

The increase in the average FFS risk score is driven by an increase in the disease component of the risk score (HCCs and interactions) that is not being offset by a decrease in the demographic component of the risk score. The disease component of the FFS risk score is increasing by approximately 3 percent per year on average while the demographic components have decreased by approximately 0.4 percent per year on average. We cannot differentiate whether the increase in the disease component of the risk score is driven by the implementation of ICD-10, either because concepts changed, more codes are available to report, or differences between how the model is calibrated and risk scores are calculated, and increasing incentives to report more diagnosis codes in the alternative payment models implemented in FFS. However, we believe that all have an effect. We note that, since MA risk scores are calculated with the same ICD-10 – to –HCC mappings, that similar increases are likely to be reflected in MA risk scores.

Figure III-1 2017 CMS-HCC Model Trend: Disease Demographic Breakout



*The FFS risk scores included in the 2017 CMS-HCC model trend that was used to estimate the normalization factor are each equal to the sum of the demographic and disease sub-components displayed.

Comment: A few commenters stated that CMS should take into consideration the Medicare Advantage coding pattern adjustment when calculating the normalization factor.

Response: The MA coding pattern difference adjustment does not affect the normalization factor, which is applied to pay plans appropriately by accounting for changes in treatment and coding practices in the FFS sector between the denominator year and the payment year to keep the average FFS score at 1.0 in the payment year.

Comment: One commenter suggested that the FFS normalization factor constitutes a substantive change in payment that must be made through regulation.

Response: The linear methodology used for calculating the normalization factor for 2020 was utilized for almost all years since the normalization factor was applied to risk scores (since 2007). We are not changing our methodology for calculating the normalization factor in 2020 from the method used in 2018 and 2019. However, if we did, we believe that the statute requires that such a change be implemented via the Advance Notice and Rate Announcement. For example, for years 2015 through 2017 we made changes to the methodology to calculate the normalization factor through the Advance Notice-Rate Announcement process. The normalization factor is a component of the methodology used to adjust payments to MA plans in

accordance with section 1853(a)(1)(C) and, therefore, appropriately finalized using the process specified in section 1853(b)(2) of the Act. As we have previously discussed in the CY2012 Rate Announcement (pp. 27-28), section 1853(b) specifies the process through which CMS proposes, adopts, and announces the capitation rates and risk adjustment methodology for the MA program. Subsection (b)(2) provides that CMS provide notice and an opportunity to submit comment on "proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement." Subsection (b)(1) provides for a final notice in which the rates and the risk and other factors used in adjusting payment will be published. CMS has consistently applied section 1853(b) of the Act to adopt MA payment methodologies in a manner intended to provide notice to interested parties, including MA organizations, and uses section 1871 of the Act and APA rulemaking to adopt rules to govern other aspects of the payment process (e.g., appeals, bidding processes) for MA plans. This notice and comment process has been in place with respect to payment issues since 1985, when CMS first began contracting with private health plans on a capitation basis, under procedures set forth in section 1876(a)(1)(F) of the Act that are identical to those in section 1853(b)(2). Interpreting section 1871 of the Act and the APA notice and comment rulemaking requirements to apply to the normalization factors would be inconsistent with this statutory scheme. Therefore, we are applying the existing methodology to determine the normalization factor that will be used for CY 2020 risk adjustment payments.

Section L. Encounter Data as a Diagnosis Source for 2020

Comment: A number of commenters concurred with CMS' proposal to increase the encounter data risk score blend to 50%, while slightly more commenters recommended that CMS maintain the current blend of 25%, and a few commenters recommended that CMS cease the use of encounter data blends in risk score calculations altogether. Many commenters continue to raise concerns regarding challenges they believe to be problematic for calculating risk scores with encounter data and cited the 2017 GAO, 2018 OIG and other external non-CMS reports that have made recommendations to improve the quality of encounter data, including the implementation of performance measures. Some commenters acknowledged that CMS continues to make significant improvements to support the complete collection and accuracy of encounter data. Others note that the move to encounter data creates a more complete data source than RAPS, will improve the ability to predict risk scores, provide transparency on the source of the encounter, and be a single source of data for MA benchmarks and risk score calibration. In addition, some commenters agreed that encounter-based risk scores and RAPS-based risk scores are converging. Most commenters supported the inclusion of RAPS inpatient data as part of easing the transition to using encounter data, although a couple of commenters questioned whether this was a temporary policy. One commenter disagreed with the inclusion of diagnoses from RAPS inpatient records in the encounter data risk score based on their independent research findings that some RAPS inpatient records could not be matched to an inpatient stay in the MedPAR (Medicare Provider Analysis and Review) data or encounter data and instead may have matched

to a physician or outpatient encounter record. Some commenters continue to express concern that an increased use of encounter data has a disproportionate effect on SNP risk scores. A few commenters requested that we release validation studies and an operational plan for remediating issues, and publicize a timeframe for using the data for payment.

Response: We appreciate the feedback related to the ongoing implementation of encounter data. CMS has continued to work with stakeholders to improve encounter data submissions and integrity. Following GAO's and OIG's recommendations, CMS developed and implemented an MA encounter data integrity plan, which includes a range of activities aimed at improving the completeness and validity of encounter data. Core activities include submission outreach, data analysis, monitoring, and compliance. These activities have improved the completeness and validity of encounter data as evidenced by the increasing volume of EDRs overall and per beneficiary and reduced error rates in submissions. Increased communication with stakeholders has resulted in a single consolidated guidance document (i.e., the Encounter Data Submission and Processing Guide), a revised user-friendly website, and additional submission guidance. Furthermore, in conversations with MAOs, CMS has asked whether the encounter data system prevents MAOs from successfully submitting data and the magnitude of the problem. The feedback has been positive. We note that a number of the reports cited by commenters are based on analyses of older submissions of encounter data records. As both CMS's and MAOs' encounter data systems have matured and stabilized, MAOs have stated that they refrain from submitting less than 1% of data due to anticipated submission issues. CMS introduced our approach to monitoring and compliance via the 2018 and 2019 Call Letters, sought stakeholder input, and will begin taking compliance actions in 2019.

In addition, we have done extensive work in recent years to improve reporting to plans, and will continue to work with plans to improve and facilitate the submission of encounter data and to assist with confirming the status of risk adjustment eligible diagnoses submitted to the Encounter Data System. It should be noted that since the beginning of encounter data collection, CMS has provided MAOs with transactional reports (277CA and MAO-002) that provide all of the information necessary for MAOs to correct and resubmit rejected data, in order to meet the requirement that they submit complete and accurate data for all services provided.

As a result of these efforts by CMS and MAOs to improve the accuracy and completeness of encounter data, CMS believes that sufficient improvements have been made to both CMS and plan systems to increase the accuracy and completeness of encounter data in order to proceed with this policy, and is finalizing the proposal to calculate 2020 risk scores by adding 50% of the risk score calculated using encounter data and FFS diagnoses (with inpatient RAPS data to supplement encounter data) and 50% of the risk score calculated using RAPS and FFS diagnoses. As previously noted, the inclusion of RAPS inpatient data is intended to be temporary. We continue to observe a limited number of plans with low encounter data submission rates, both relative to RAPS and relative to submissions from similar organizations, and understand that some plans may require additional time or technical support to improve

submissions. The inclusion of RAPS inpatient diagnoses will help to minimize any potential impact from incomplete data for the limited number of plans that may face operational challenges submitting encounter data records. We will continue to monitor the completeness of encounter data submissions for all plans and determine whether to continue supplementing diagnoses from RAPS inpatient records each year.

In addition, CMS analysis shows that when comparing RAPS-based risk scores calculated using the 2017 CMS-HCC model to encounter data-based risk scores calculated using the payment count model, the risk scores are converging. In addition, since the new 2020 model is calibrated specifically to calculate risk scores based on encounter data, we proposed the 50/50 encounter data and RAPS data risk score blend consistent with the 50/50 blend of the new and old risk adjustment models. Therefore, finalizing as proposed aligns the new model phase in percentage with the RAPS/encounter data blend for 2020 and minimizes the potential burden to stakeholders and CMS of calculating multiple blends between each of the models.

Comment: While most commenters acknowledged that CMS has improved communication and engagement with stakeholders, many commenters continue to detail concerns about operational challenges such as multiple revisions of the encounter data system reports that identify diagnoses eligible for risk adjustment, changing deadlines for submitting encounter data for risk adjustment, and multiple risk score reconciliations as a reason to not increase the proportion of encounter data in the risk score blend.

Response: We appreciate the feedback and understand the operational concerns. As part of our broader encounter data integrity plan, CMS has been conducting outreach to provide technical assistance and solicit feedback on technical issues through various channels, including 1-on-1 calls, site visits, user group calls, listening forums, and an on-site training. In response to feedback, we have done extensive work on the reports to MAOs that indicate which diagnoses submitted to the Encounter Data System are eligible for risk adjustment. These improvements have resolved the vast majority of technical issues and satisfied stakeholder requests for enhancements to the content and format of these reports. With the exception of a few remaining issues (less than 1% of all encounter data record submissions in 2019 are affected), these reports have stabilized and stakeholder feedback on the format and content of these reports has generally been positive. We expect to resolve these remaining issues in the near future, and as such, commenters' concerns related to data submitted for payment in prior years do not preclude CMS from increasing the percentage of encounter data in the risk score blend for 2020. We are committed to continuing our work with stakeholders to resolve technical challenges with encounter data reports and risk score calculation and welcome additional feedback moving forward.

Comment: A few commenters suggested that encounter data use for risk adjusted payment is inconsistent with the move toward value-based care.

Response: We appreciate the comment. Section 1853(a)(1)(C) of the Act requires that Medicare Advantage payments be adjusted based on such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status. To risk adjust payments, CMS requires organizations offering Medicare Advantage plans and certain other Medicare private health plans to submit risk adjustment data that characterize the context and purpose of each item and service provided to a Medicare enrollee, as well as clinical condition information, as described in regulation at 42 C.F.R. § 422.310. While CMS does not dictate the price structures or amounts that MA organizations pay their contracted providers, we believe that MAOs collect either claims or encounters from providers for their own use and, therefore, have this data available to them.

Comment: Some commenters inquired as to how much of the difference in risk scores is attributable to the multiple model changes in recent years versus increased use of encounter data.

Response: Thank you for your comments. We understand how important model stability is for stakeholders. However, we note that the changes made to the model in 2017 (V22), were in response to concerns both stakeholders and CMS had on how well the model predicted for dual eligible beneficiaries. The most recent changes adding condition counts are revisions CMS was required to make by the amendments to section 1853 by the 21st Century Cures Act. Also, by identifying diagnoses for model calibration using the same approach used for encounter data records, the models are more closely aligned with the data used to calculate risk scores.

Comment: Some commenters raised concern that estimates in the Advance Notice and in the President's Budget indicate the transition to encounter data is a method to reduce funding to the Medicare Advantage program.

Response: We expect that, as the quality of encounter data submissions continues to improve and more accurately reflect the items and services rendered to MA beneficiaries, any differential between risk adjusted payments using encounter data versus RAPS will continue to narrow.

Comment: Some commenters expressed support for CMS' decision to continue the method of calculating risk scores using encounter data, RAPS, and FFS claims for PACE Organizations.

Response: We appreciate the support and for 2020 are finalizing the proposal to pool risk adjustment-eligible diagnoses from the following sources to calculate a single risk score (with no weighting): (1) encounter data, (2) RAPS, and (3) FFS claims. This approach will apply to Part C, ESRD, and Part D risk scores for PACE enrollees. For 2020 we will continue to use the 2019 ESRD model to calculate PACE ESRD risk scores. Non-ESRD PACE risk scores will be calculated using the 2017 CMS-HCC model.

Comment: A few commenters expressed concern regarding the administrative burden that encounter data creates for providers.

Response: We appreciate the concerns of the commenters. In providing submission guidance to plans, our goal is to minimize administrative burden, while ensuring that the data submitted are accurate and complete. We maintain a variety of data checks on key elements to ensure data element quality. We will continue to work with interested stakeholders on technical and operational issues to improve the acceptance, completeness, and quality of encounter data.

Attachment IV. Responses to Public Comments on Part D Payment Policy

Section A. Update of the RxHCC Model

Comment: The majority of commenters supported the use of the RxHCC model calibrated on 2014/2015 data in 2020, indicating that this version of the model provides more stability than the 2015/2016 model.

Response: We will implement the 2014/2015 RxHCC model for payment year 2020.

Comment: A few commenters asserted that recalibration of the RxHCC model using updated data years should not be implemented until there is certainty that the impact of including ICD-10 diagnoses has been accounted for. One commenter supported the implementation of the 2015/2016 RxHCC model for 2020 in order to reflect more recent utilization and cost information, and therefore more accurate risk-adjusted payments to plans. Another commenter expressed concern that the proposed RxHCC models for 2020 may not adequately account for programmatic changes pending with CMS and HHS that could have a material impact (e.g., on the bid and plan benefits) and advocated for delaying recalibration until the proposed rules for Part D are finalized and that those finalized policies are accounted for (if necessary) in an updated RxHCC model.

Response: As we stated in the 2020 Advance Notice, the 2020 model (i.e., the 2014/2015 RxHCC model) has the same structure and calibration years as the model implemented in 2018 and is updated based on the 2020 benefit structure gap parameters. Adjustments made to PDE data in preparation for model calibration are similar to those from previous years' model calibrations in that we incorporated the payment year (in this case, 2020) plan liability in the coverage gap into the prediction year expenditure data. We appreciate concerns regarding the benefit of calibrating the RxHCC model on more recent utilization and cost information and the consideration of the model's reflection of Part D payment policy. The HCCs underlying our risk adjustment models are created using ICD-9 codes, and we recognize that they may be different when we recreate them using ICD-10 codes. For 2020, CMS will maintain the continued use of 2014/2015 data for calibration and will continue to consider commenters' calibration recommendations in the future.

Section B. Encounter Data as a Diagnosis Source for 2020

Please refer to Section L in Attachment III, above, for comments and responses on the use of encounter data as a diagnosis source in 2020.

Section C. Part D Risk Sharing

Comment: Several commenters agreed with our analytical approach regarding the Part D risk sharing parameters.

Response: We appreciate the support.

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2020

Comment: The majority of commenters stated their understanding that congressional action is needed to change the calculation of the out-of-pocket threshold, but expressed significant concern about the large increase and encouraged CMS to work with Congress to implement statutory changes as this represents a substantial increase for beneficiaries. A few commenters recommended that CMS find a way to mitigate this significant increase in out-of-pocket expenditures even absent congressional intervention.

Response: CMS does not have discretion to alter these formulas as set forth by Congress, and therefore will implement the benefit parameters for 2020 in accordance with the statutory requirements of current law. However, we appreciate these comments and share the significant concerns raised about the impact these changes may have on beneficiaries in 2020. While these parameters must be implemented as Congress designed, CMS remains committed to addressing the rising cost of prescription drugs for seniors.

Comment: A significant number of commenters noted the effects of increased out-of-pocket expenditures on beneficiaries, such as lower medication compliance, utilization, and adherence, as well as therapy abandonment, and higher premiums. These commenters also asserted that the beneficiaries most affected by this change are those who are most vulnerable with complex and serious healthcare expenses requiring specialty or other expensive single-source brand drugs for which lower cost alternatives are not available and could experience adverse healthcare outcomes from not being able to afford their medications. Several commenters expressed concern about how the increase in the benefit parameters, particularly the out-of-pocket threshold, will interact with overall drug cost patterns that are increasing rapidly year-over-year. These commenters encouraged CMS to continue to monitor and identify strategies for addressing the escalating cost of drugs and the impact on Part D enrollees as these trends have serious financial implications for beneficiaries, particularly those paying coinsurance.

Response: As noted above, CMS shares the significant concerns raised about the impact the increased out-of-pocket threshold and updated benefit parameters will have on beneficiaries in 2020, particularly in light of escalating year-over-year costs. However, CMS does not have discretion to alter these formulas as set forth by Congress, and therefore will implement the benefit parameters for 2020 in accordance with the statutory requirements of current law. While these parameters must be implemented as Congress designed, CMS remains committed to monitoring the effects of these and other changes on beneficiaries in the Part D program and continually seeking opportunities to implement policies within our legal authority to make drugs more affordable. CMS also recently updated the prescription drug pricing and spending data dashboards, which adds information on the manufacturers that are responsible for price increases

and includes pricing and spending data for thousands of drugs across Medicare Parts B and D and Medicaid in order to provide additional transparency on the drug pricing trends CMS is monitoring.[5] CMS is fully committed to putting American patients first by addressing the rising cost of prescription drugs for the American consumer. The Administration has made drug pricing one of its top priorities to bring immediate attention to resolving this issue for all American consumers. In connection with these commitments, the Administration issued a blueprint, American Patients First, to address many of the challenges and opportunities impacting American patients and consumers. CMS and HHS have also recently issued notices of proposed rulemaking and several demonstrations, some of which are still open for public comment, to advance this commitment. CMS is carefully reviewing comments received on those proposals issued in Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P), and CMS looks forward to receiving comments on other policies and proposals that remain open for public comment and consideration.

Comment: A few commenters recommended that CMS engage in a proactive beneficiary education campaign on this issue to explain the underlying cause of the increase in their out-of-pocket liability, including the statutory origins, and share the educational strategy with Part D sponsors. A couple of these commenters expressed concern about the impact the increased out-of-pocket threshold will have on CAHPS survey results and plan satisfaction.

Response: We appreciate these comments and remain committed to ensuring that all information necessary to make knowledgeable, appropriate, responsible and personal choices is readily available to beneficiaries before and during the annual open enrollment period. As part of this commitment we have made significant improvements to Plan Finder to ensure beneficiaries have accurate information to compare drug costs from plan to plan in making their 2020 enrollment decisions. Notwithstanding the foregoing, CMS includes the benefit parameters, the underlying methodology as well as an explanation of the driving forces behind any changes in the benefit parameters, in the Advance Notice to ensure that plan sponsors have sufficient time to both incorporate these requirements into the development of their benefit as well as to incorporate any necessary changes into their marketing materials.

Comment: We received one comment inquiring about one of the 2019 values presented in the Part D Benefit Parameters chart on Page 67 of Part II of the 2020 Advance Notice. In the 2019 Rate Announcement, the value for "Estimated Total Covered Part D Spending for Applicable Beneficiaries" was $8,139.54, however, in the 2020 Advance Notice, this same item had a value of $8,906.55 for 2019 in the chart. This commenter requested that CMS provide clarification in the 2020 Rate Announcement as to which amount is correct for 2019.

[5] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html

Response: We appreciate this being brought to our attention. The correct value for 2019 is $8,139.54. We have updated the chart in attachment V below to reflect this correct 2019 value.

Section E. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap

Comment: One commenter requested clarification as to how the Call Letter recommendation to establish a $0 copay for vaccines would interact with the fact that in 2020 applicable beneficiaries are to pay 25% of dispensing and vaccination fees for applicable drugs in the coverage gap.

Response: Consistent with our policy on liability for dispensing and vaccine administration fees, as described in the Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, applicable beneficiaries will pay a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance in the coverage gap, after the application of the coverage gap discount program discount when applicable. The Part D sponsor will pay the remainder of the dispensing fee and vaccine administration fee, if any. Therefore, in 2020, applicable beneficiaries will pay 25 percent and plans will pay 75 percent of dispensing fees and vaccine administration fees (if any) for applicable drugs in the coverage gap. In the event that a beneficiary has a copay for an applicable drug in the coverage gap phase, not coinsurance, the amount of the copay a beneficiary is liable for in that dispensing event should represent the full extent of the beneficiary's liability. If a vaccine or dispensing fee is charged by the pharmacy to the Part D sponsor, no portion of that fee should be passed on to the beneficiary *in addition* to that set copay amount in the gap. The established copay should already account for any such expenditures so that it meets actuarial equivalence.

Section F. Part D Calendar Year Employer Group Waiver Plans

Comment: One commenter expressed support for the proposal to continue to pay Calendar Year Part D EGWPs prospective reinsurance in 2020.

Response: We appreciate the support.

Attachment V. Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Table V-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2019	Prior year revisions	Annual percentage increase for 2020
API: Applied to all parameters but (2)	5.25%	-0.04%	5.21%
September CPI (all items, U.S. city average): Applied to (2)	2.27%	0.32%	2.59%

Part D Benefit Parameters

	2019	2020
Standard Benefit		
Deductible	$415	$435
Initial Coverage Limit	$3,820	$4,020
Out-of-Pocket Threshold (1)	$5,100	$6,350
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,653.75	$9,038.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$8,139.54	$9,719.38
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$3.40	$3.60
Other	$8.50	$8.95
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services] [category code 3] (5)	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug/Biosimilar (6)	$1.25	$1.30
Other (6)	$3.80	$3.90
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL [category code 1]		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug/Biosimilar	$3.40	$3.60
Other	$8.50	$8.95
Above Out-of-Pocket Threshold	$0.00	$0.00

	2019	2020
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI, income at or below 135% FPL and resources ≤ $9,060 (individuals, 2019) or ≤ $14,340 (couples, 2019) [category code 1] (7)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug/Biosimilar	$3.40	$3.60
Other	$8.50	$8.95
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $14,100 (individual, 2019) or $28,150 (couples, 2019) [category code 4] (7)		
Deductible (6)	$85.00	$89.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug/ Biosimilar	$3.40	$3.60
Other	$8.50	$8.95
Retiree Drug Subsidy Amounts		
Cost Threshold	$415	$435
Cost Limit	$8,500	$8,950

(1) For 2020 the Act requires the out-of-pocket threshold to be calculated as if the out-of-pocket threshold for years 2014 through 2019 had been subject to the respective annual percentage increase (API) values for those years. Pursuant to section 1860D-2(b)(4)(B)(i)(IV) of the Act, for 2019, the out-of-pocket threshold increase was the lesser of the API or the July CPI plus two percentage points.
(2) September CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(3) For a beneficiary who is not considered an "applicable beneficiary," as defined at section 1860D-14A(g)(1), and is not eligible for the Coverage Gap Discount Program, this is the amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.
(4) For a beneficiary who is considered an "applicable beneficiary," as defined at section 1860D-14A(g)(1), and is eligible for the Coverage Gap Discount Program, this is the estimated average amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.
(5) Per section 1860D-14(a)(1)(D)(i) of the Act, full-benefit dual eligible beneficiaries qualify for zero cost-sharing if they would be institutionalized individuals (or couple) if the individuals (couple) were not receiving home and community-based services.
(6) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2019 values of $85.06, $1.27, and $3.80, respectively.
(7) The actual amount of resources allowable will be updated for contract year 2020. Additionally, these amounts include $1,500 per person for burial expenses. See the HPMS memorandum titled, "2019 Resource and Cost-Sharing Limits for Low-Income Subsidy (LIS)" for additional details.

Section A. Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API)

Section 1860D-2(b)(6) of the Act defines the API as "the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify." The following parameters are updated using the "annual percentage increase":

Deductible: From $415 in 2019 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $3,820 in 2019 and rounded to the nearest multiple of $10.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $3.40 per generic, preferred drug that is a multi-source drug or biosimilar and $8.50 for all other drugs in 2019, rounded to the nearest multiple of $0.05.

Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low-Income Full Subsidy Eligible Enrollees: From $3.40 per generic, preferred drug that is a multi-source drug or biosimilar and $8.50 for all other drugs in 2019, rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $85[6] in 2019 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $3.40 per generic, preferred drug that is a multi-source drug or biosimilar and $8.50 for all other drugs in 2019, rounded to the nearest multiple of $0.05.

Annual Percentage Increase for Out-of-Pocket Threshold

Section 1860D-2(b)(4) of the Act modified how the out-of-pocket threshold was to be calculated for 2014 through 2019. For 2014 and 2015, the Act required that the out-of-pocket threshold be updated by the API minus 0.25 percentage point, while for contract years 2016 through 2019 the Act required that the out-of-pocket threshold be updated from the previous year by the lesser of (1) the API or (2) two percentage points plus the annual percentage increase in CPI.

For 2020 and subsequent years, the Act requires the out-of-pocket threshold to be calculated using the API. Moreover, for 2020, the out-of-pocket threshold must be calculated as if the calculation of the out-of-pocket threshold for years 2014 through 2019 had not be modified (i.e.,

[6] Per section 1860D-14(a)(4)(B) of the Act, the update for the deductible for partial low income subsidy eligible enrollees is applied to the unrounded 2019 value of $85.06.

as if the thresholds for each of years 2014 through 2019 had been updated using the API). The threshold is increased from $5,100 in 2019 and rounded to the nearest multiple of $50.

Section B. Annual Percentage Increase in Consumer Price Index (CPI)

Annual Percentage Increase in Consumer Price Index, September (September CPI)

Section 1860D-14(a)(4) of the Act specifies that CMS use the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year to update the maximum copayment amounts up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal Poverty Level. These copayments are increased from $3.40 per generic, preferred drug that is a multi-source drug or biosimilar, and from $8.50 for all other drugs in 2019, and rounded to the nearest multiple of $0.05 and $0.10 respectively.[7]

Section C. Calculation Methodology

Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API)

For contract years 2007 and 2008, the APIs, as defined in section 1860D-2(b)(6) of the Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with contract year 2009, the APIs are based on Part D program data. For the contract year 2020 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2018–July\ 2019}{August\ 2017–July\ 2018} = \frac{\$3{,}925.20}{\$3{,}729.35} = 1.0525$$

In the formula, the average per capita cost for August 2017 – July 2018 ($3,729.35) is calculated from actual Part D PDE data, and the average per capita cost for August 2018 – July 2019 ($3,925.20) is calculated based on actual Part D PDE data incurred from August 2018 – December 2018 and projected through July 2019.

The 2020 benefit parameters reflect the 2019 annual percentage trend, as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now calculated as summarized by Table IV-1.

[7] Per section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2019 values of $1.27 for multi-source generic or preferred drugs, and $3.80 for all other drugs.

Table IV-1. Revised Prior Years' Annual Percentage Increases

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	7.30%	7.30%
2008	5.92%	5.92%
2009	4.69%	4.69%
2010	3.14%	3.14%
2011	2.36%	2.36%
2012	2.15%	2.15%
2013	2.53%	2.53%
2014	−3.14%	−3.14%
2015	10.12%	10.12%
2016	9.92%	9.90%
2017	4.00%	3.98%
2018	2.02%	1.90%
2019	3.96%	4.09%

Accordingly, the 2020 benefit parameters reflect a multiplicative update of -0.04% percent for prior year revisions. In summary, the 2019 parameters outlined in Section A are updated by 5.21% percent for 2020, as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2019	5.25%
Prior year revisions	-0.04%
Annual percentage increase for 2020	5.21%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase for Out-of-Pocket Threshold

In accordance with section 1860D-2(b)(4), we calculated the change in the Out-of-Pocket threshold using the 2013 threshold value of $4,750 as our starting point. To calculate the 2020 value, we applied the API values from years 2014 through 2019 as published in the respective final Rate Announcements for those years, and the 2020 API described above. The calculation is as follows:

1. The starting point is the 2013 Out-of-Pocket threshold of $4,750.

2. We apply the published API for 2014, as this is the percentage that would have been applied absent the modification.

3. We round the resulting value to the nearest $50.

4. We repeat steps 1 through 3 for each subsequent year through 2019.

5. We apply the 2020 API and round to the nearest $50.

Note that we are applying the published API for each year, rather than the revised API as of today. This is consistent with the requirement to calculate the threshold as though there had been no modification and ensures that the threshold value appropriately accounts for prior period restatements. The resulting 2020 Out-of-Pocket threshold value is $6,350.

Annual Percentage Increase in Consumer Price Index, September (September CPI)

To ensure that plan sponsors and CMS have sufficient time to incorporate cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, CMS includes in its methodology to calculate the annual percentage increase in the CPI for the 12-month period ending in September 2019, an estimate of the September 2019 CPI based on projections from the President's FY2020 Budget.

The September 2018 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2020 is calculated as follows:

$$\frac{\text{Projected September 2019 CPI}}{\text{Actual September 2018 CPI}} \; or \; \frac{258.2}{252.4} = 1.0227^{8}$$

(Source: President's FY2020 Budget and Bureau of Labor Statistics, Department of Labor)

The 2020 benefit parameters reflect the 2019 annual percentage trend in the September CPI of 2.27 percent, as well as a revision to the prior estimate for the 2018 CPI increase over the 12-month period ending in September 2018. Based on the actual reported CPI for September 2018, the September 2018 CPI increase is now estimated to be 2.28 percent. Accordingly, the 2020 update reflects a 0.32 percent multiplicative correction for the revision to last year's estimate. In summary, the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal Poverty Level are updated by 2.59 percent for 2020, as summarized by Table IV-3.

[8] Values are carried to additional decimal places and may not agree to the rounded values presented above.

Table IV-3. Cumulative Annual Percentage Increase in September CPI

Annual percentage trend for September 2019	2.27%
Prior year revisions	0.32%
Annual percentage increase for 2020	2.59%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree to the rounded values presented above.

Section D. Retiree Drug Subsidy Amounts

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are also updated using the API, as defined previously in this document. The updated cost threshold is rounded to the nearest multiple of $5 and the updated cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $405 and $8,350, respectively, for plans that end in 2018, and as $415 and $8,500 for plans that end in 2019. For 2020, the cost threshold is $435 and the cost limit is $8,950.

Section E. Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries

For 2020, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $9,719.38. The figure is calculated given the following basic assumptions:

- 100 percent beneficiary cost-sharing in the deductible phase.
- 25 percent beneficiary cost-sharing in the initial coverage phase.
- 25 percent beneficiary cost-sharing for non-applicable drugs purchased in the coverage gap phase of the benefit.
- 95 percent cost-sharing for the ingredient cost and sales tax for applicable drugs purchased in the coverage gap phase of the benefit—comprised of 25 percent beneficiary coinsurance and 70 percent Coverage Gap Discount Program discount.
- 25 percent cost-sharing for the dispensing and vaccine administration fees for applicable drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.105 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 75 percent reduction in cost-sharing for dispensing and vaccine administration fees results in an overall reduction of 0.074 percent to 94.93 percent in cost-sharing for applicable (brand) drugs in the coverage gap.

The estimated total covered Part D spending at out-of-pocket (OOP) threshold for applicable beneficiaries is calculated as follows:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad or \quad \$4{,}020 + \frac{\$5{,}018.75}{88.0579\%} = \$9{,}719.38$$

- *ICL* is the Initial Coverage Limit equal to $4,020
- *100 percent beneficiary cost-sharing in the gap* is the estimated total drug spending in the gap assuming 100 percent coinsurance and is equivalent to:

  *(*OOP threshold) – (OOP costs up to the ICL) *or* $6,350 − $1,331.25= $5,018.75

- *Weighted gap coinsurance factor* is calculated as follows:

  (Brand Gross Drug Cost Below Catastrophic [GDCB] % for non-LIS × 94.93% gap cost-sharing for applicable drugs) + (Generic GDCB % for non-LIS × 25% gap cost-sharing for non-applicable drugs)

  or

  (90.18% × 94.93%) + (9.82% × 25%) =88.0579%[9]

  - *Brand GDCB % for non-LIS* is the percentage of gross covered drug costs below the OOP threshold for applicable beneficiaries (i.e., non-LIS) attributable to applicable drugs, as reported on the 2018 PDEs.
  - *Gap cost-sharing for applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for applicable drugs in the coverage gap, where:
    - *Coinsurance for applicable drugs* = is calculated as follows:

      [(percentage of gross covered brand drug costs attributable to ingredient cost and sales tax) × (cost-sharing percentage)] + [(percentage of gross covered brand drug costs attributable to dispensing and vaccine administration fees) × (cost-sharing coinsurance percentage)]

      or

      94.93% = [(99.895% × 95%) + (0.105% × 25%)]
  - *Generic GDCB % for non-LIS* is the percentage of gross covered drug costs below the OOP threshold for applicable beneficiaries (i.e., non-LIS) attributable to non-applicable drugs as reported on the 2018 PDEs.

[9] Values are carried to additional decimal places and may not agree to the rounded values presented above.

- *Gap cost-sharing for non-applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for non-applicable drugs in the coverage gap.

Attachment VI. CMS-HCC, ESRD and RxHCC Risk Adjustment Factors

Table VI-1. 2020 Alternative Payment Condition Count Model Relative Factors for Continuing Enrollees

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
Female								
0-34 Years		-	0.241	-	0.349	-	0.383	0.902
35-44 Years		-	0.315	-	0.349	-	0.414	1.105
45-54 Years		-	0.348	-	0.374	-	0.418	1.043
55-59 Years		-	0.379	-	0.434	-	0.414	1.065
60-64 Years		-	0.428	-	0.490	-	0.412	1.067
65-69 Years		0.323	-	0.441	-	0.359	-	1.245
70-74 Years		0.386	-	0.519	-	0.406	-	1.150
75-79 Years		0.451	-	0.593	-	0.476	-	1.014
80-84 Years		0.528	-	0.716	-	0.550	-	0.882
85-89 Years		0.641	-	0.865	-	0.653	-	0.798
90-94 Years		0.783	-	0.987	-	0.783	-	0.668
95 Years or Over		0.787	-	1.041	-	0.873	-	0.501
Male								
0-34 Years		-	0.156	-	0.240	-	0.389	1.101
35-44 Years		-	0.199	-	0.235	-	0.282	1.002
45-54 Years		-	0.241	-	0.307	-	0.313	0.965
55-59 Years		-	0.287	-	0.402	-	0.340	1.017
60-64 Years		-	0.330	-	0.526	-	0.373	1.061
65-69 Years		0.308	-	0.494	-	0.370	-	1.288
70-74 Years		0.394	-	0.600	-	0.427	-	1.329
75-79 Years		0.473	-	0.710	-	0.500	-	1.317
80-84 Years		0.556	-	0.803	-	0.544	-	1.207
85-89 Years		0.686	-	1.000	-	0.659	-	1.122
90-94 Years		0.841	-	1.142	-	0.834	-	0.989
95 Years or Over		0.986	-	1.267	-	1.047	-	0.821
Medicaid and Originally Disabled Interactions								

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
Medicaid		-	-	-	-	-	-	0.061
Originally Disabled, Female		0.250	-	0.173	-	0.136	-	-
Originally Disabled, Male		0.147	-	0.182	-	0.083	-	-
Disease Coefficients	**Description Label**							
HCC1	HIV/AIDS	0.335	0.287	0.595	0.396	0.482	0.200	1.722
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.352	0.414	0.453	0.530	0.316	0.297	0.324
HCC6	Opportunistic Infections	0.424	0.740	0.572	0.803	0.318	0.658	0.534
HCC8	Metastatic Cancer and Acute Leukemia	2.659	2.714	2.566	2.801	2.455	2.659	1.303
HCC9	Lung and Other Severe Cancers	1.024	0.910	1.010	1.001	1.001	0.880	0.623
HCC10	Lymphoma and Other Cancers	0.675	0.663	0.717	0.756	0.648	0.667	0.461
HCC11	Colorectal, Bladder, and Other Cancers	0.307	0.345	0.317	0.355	0.330	0.351	0.294
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.150	0.212	0.158	0.212	0.154	0.181	0.210
HCC17	Diabetes with Acute Complications	0.302	0.351	0.340	0.423	0.326	0.373	0.440
HCC18	Diabetes with Chronic Complications	0.302	0.351	0.340	0.423	0.326	0.373	0.440
HCC19	Diabetes without Complication	0.105	0.124	0.107	0.145	0.087	0.122	0.178
HCC21	Protein-Calorie Malnutrition	0.455	0.674	0.693	0.723	0.457	0.679	0.267
HCC22	Morbid Obesity	0.250	0.183	0.383	0.297	0.233	0.204	0.455
HCC23	Other Significant Endocrine and Metabolic Disorders	0.194	0.378	0.211	0.299	0.174	0.319	0.379
HCC27	End-Stage Liver Disease	0.882	1.065	1.111	1.101	0.729	0.887	0.874
HCC28	Cirrhosis of Liver	0.363	0.334	0.411	0.365	0.403	0.341	0.485
HCC29	Chronic Hepatitis	0.147	0.314	0.042	0.292	0.181	0.238	0.485
HCC33	Intestinal Obstruction/Perforation	0.219	0.503	0.258	0.538	0.232	0.552	0.352
HCC34	Chronic Pancreatitis	0.287	0.580	0.349	0.762	0.371	0.597	0.422

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC35	Inflammatory Bowel Disease	0.308	0.523	0.275	0.551	0.275	0.543	0.355
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.401	0.378	0.558	0.682	0.443	0.435	0.401
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.421	0.367	0.371	0.328	0.347	0.264	0.292
HCC46	Severe Hematological Disorders	1.372	3.566	1.214	4.309	1.234	4.138	0.799
HCC47	Disorders of Immunity	0.665	0.860	0.452	0.691	0.674	0.594	0.576
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.192	0.312	0.221	0.298	0.186	0.330	0.190
HCC51	Dementia With Complications	0.346	0.224	0.453	0.256	0.420	0.257	-
HCC52	Dementia Without Complication	0.346	0.224	0.453	0.256	0.420	0.257	-
HCC54	Substance Use with Psychotic Complications	0.329	0.543	0.538	0.896	0.372	0.679	0.178
HCC55	Substance Use Disorder, Moderate/Severe, or Substance Use with Complications	0.329	0.279	0.538	0.356	0.372	0.275	0.178
HCC56	Substance Use Disorder, Mild, Except Alcohol and Cannabis	0.329	0.247	0.538	0.348	0.372	0.275	0.178
HCC57	Schizophrenia	0.524	0.352	0.570	0.381	0.495	0.309	0.187
HCC58	Reactive and Unspecified Psychosis	0.393	0.352	0.570	0.231	0.449	0.239	0.187
HCC59	Major Depressive, Bipolar, and Paranoid Disorders	0.309	0.164	0.299	0.127	0.306	0.109	0.187
HCC60	Personality Disorders	0.309	0.108	0.299	0.100	0.255	0.065	-
HCC70	Quadriplegia	1.242	1.001	1.038	1.000	1.000	1.134	0.549
HCC71	Paraplegia	1.068	0.739	0.921	0.957	1.000	0.933	0.492
HCC72	Spinal Cord Disorders/Injuries	0.481	0.369	0.532	0.377	0.512	0.336	0.289
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.999	1.132	1.101	1.245	0.687	0.933	0.476
HCC74	Cerebral Palsy	0.339	0.098	-	-	0.114	-	-

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	0.472	0.481	0.407	0.404	0.287	0.314	0.332
HCC76	Muscular Dystrophy	0.518	0.621	0.413	0.597	-	0.286	0.356
HCC77	Multiple Sclerosis	0.423	0.566	0.742	0.789	0.276	0.460	-
HCC78	Parkinson's and Huntington's Diseases	0.606	0.501	0.601	0.443	0.536	0.430	0.159
HCC79	Seizure Disorders and Convulsions	0.220	0.196	0.237	0.139	0.257	0.169	0.065
HCC80	Coma, Brain Compression/Anoxic Damage	0.486	0.274	0.511	0.105	0.729	0.134	-
HCC82	Respirator Dependence/Tracheostomy Status	1.000	0.781	2.183	1.465	0.836	0.769	1.622
HCC83	Respiratory Arrest	0.354	0.400	0.902	0.531	0.361	0.769	0.511
HCC84	Cardio-Respiratory Failure and Shock	0.282	0.385	0.492	0.531	0.361	0.343	0.313
HCC85	Congestive Heart Failure	0.331	0.447	0.371	0.486	0.336	0.422	0.203
HCC86	Acute Myocardial Infarction	0.195	0.264	0.377	0.425	0.293	0.379	0.366
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.195	0.264	0.302	0.425	0.276	0.379	0.366
HCC88	Angina Pectoris	0.135	0.111	0.034	0.152	0.149	0.149	0.366
HCC96	Specified Heart Arrhythmias	0.268	0.262	0.384	0.308	0.264	0.281	0.252
HCC99	Intracranial Hemorrhage	0.230	0.170	0.380	0.486	0.230	0.163	0.111
HCC100	Ischemic or Unspecified Stroke	0.230	0.146	0.380	0.324	0.230	0.163	0.111
HCC103	Hemiplegia/Hemiparesis	0.437	0.281	0.487	0.296	0.438	0.310	-
HCC104	Monoplegia, Other Paralytic Syndromes	0.331	0.270	0.345	0.258	0.300	0.164	-
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.488	1.521	1.724	1.748	1.504	1.525	0.867
HCC107	Vascular Disease with Complications	0.383	0.464	0.565	0.653	0.463	0.450	0.299

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC108	Vascular Disease	0.288	0.301	0.294	0.267	0.297	0.314	0.093
HCC110	Cystic Fibrosis	0.510	2.676	0.509	3.516	0.392	3.051	0.593
HCC111	Chronic Obstructive Pulmonary Disease	0.335	0.246	0.430	0.331	0.358	0.267	0.311
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.219	0.237	0.161	0.275	0.200	0.229	0.110
HCC114	Aspiration and Specified Bacterial Pneumonias	0.517	0.236	0.641	0.375	0.514	0.198	0.156
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.130	-	0.258	-	0.093	0.082	0.156
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.222	0.231	0.271	0.269	0.182	0.201	0.394
HCC124	Exudative Macular Degeneration	0.521	0.314	0.298	0.145	0.393	0.158	0.217
HCC134	Dialysis Status	0.435	0.406	0.683	0.594	0.446	0.480	0.468
HCC135	Acute Renal Failure	0.435	0.406	0.683	0.594	0.446	0.480	0.468
HCC136	Chronic Kidney Disease, Stage 5	0.289	0.231	0.260	0.323	0.280	0.261	0.245
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.289	0.105	0.260	0.138	0.280	0.039	0.201
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	0.069	0.021	0.017	-	0.043	-	0.092
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.028	2.097	2.463	2.582	2.028	2.512	0.854
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.069	1.212	1.471	1.380	1.162	0.925	0.322
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.656	0.628	0.863	0.467	0.649	0.824	0.322
HCC161	Chronic Ulcer of Skin, Except Pressure	0.515	0.592	0.727	0.583	0.541	0.542	0.294
HCC162	Severe Skin Burn or Condition	0.224	0.506	0.162	0.308	-	0.324	-
HCC166	Severe Head Injury	0.486	0.274	0.511	0.105	0.729	0.134	-
HCC167	Major Head Injury	0.077	-	0.144	0.025	0.034	0.019	-

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC169	Vertebral Fractures without Spinal Cord Injury	0.476	0.369	0.532	0.377	0.512	0.336	0.250
HCC170	Hip Fracture/Dislocation	0.350	0.394	0.409	0.469	0.354	0.333	-
HCC173	Traumatic Amputations and Complications	0.208	0.172	0.221	0.525	0.176	0.180	0.092
HCC176	Complications of Specified Implanted Device or Graft	0.582	0.911	0.680	0.982	0.520	0.832	0.469
HCC186	Major Organ Transplant or Replacement Status	0.832	0.445	0.728	0.865	0.438	0.613	1.046
HCC188	Artificial Openings for Feeding or Elimination	0.534	0.755	0.742	0.770	0.520	0.732	0.514
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.519	0.437	0.795	0.934	0.697	0.626	0.357
Disease Interactions								
HCC47_gCancer	Immune Disorders*Cancer	0.838	0.460	0.853	0.679	0.656	0.601	-
Diabetes_CHF	Congestive Heart Failure*Diabetes	0.121	0.024	0.192	0.043	0.113	-	0.169
CHF_gCopdCF	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.155	0.121	0.230	0.154	0.158	0.141	0.191
HCC85_gRenal_v24	Congestive Heart Failure*Renal	0.156	0.411	0.187	0.461	0.186	0.382	-
gCopdCF_CARD_RESP_FAIL	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.363	0.379	0.528	0.455	0.392	0.479	0.414
HCC85_HCC96	Congestive Heart Failure*Specified Heart Arrhythmias	0.085	0.282	0.138	0.361	0.101	0.303	-
gSubstanceUseDisorder_gPsych	Substance Use Disorder*Psychiatric	-	0.138	-	0.191	-	0.201	-
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	-	-	-	-	-	-	0.155
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	-	-	-	-	-	-	0.474
ART_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	-	-	-	-	-	-	0.359

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
gCopdCF_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	-	-	-	-	-	-	0.216
ASP_SPEC_BACT_PNEUM_PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	-	-	-	-	-	-	0.472
SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	-	-	-	-	-	-	0.346
SCHIZOPHRENIA_gCopdCF	Schizophrenia*Chronic Obstructive Pulmonary Disease	-	-	-	-	-	-	0.417
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	-	-	-	-	-	-	0.127
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	-	-	-	-	-	-	0.573
Disabled/Disease Interactions								
DISABLED_HCC85	Disabled, Congestive Heart Failure	-	-	-	-	-	-	0.279
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer	-	-	-	-	-	-	0.544
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	-	-	-	-	-	-	0.473
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	-	-	-	-	-	-	0.456
DISABLED_HCC77	Disabled, Multiple Sclerosis	-	-	-	-	-	-	0.496
DISABLED_HCC6	Disabled, Opportunistic Infections	-	-	-	-	-	-	0.405
Payment HCC Counts								
D1	1 payment HCC	-	-	-	-	-	-	-
D2	2 payment HCCs	-	-	-	-	-	-	-
D3	3 payment HCCs	-	-	-	-	-	-	-
D4	4 payment HCCs	0.006	-	-	-	-	-	-

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
D5	5 payment HCCs	0.042	0.043	-	0.055	0.037	0.083	-
D6	6 payment HCCs	0.077	0.131	0.040	0.167	0.071	0.117	-
D7	7 payment HCCs	0.126	0.201	0.057	0.269	0.080	0.291	-
D8	8 payment HCCs	0.214	0.441	0.095	0.424	0.125	0.452	-
D9	9 payment HCCs	0.258	0.441	0.156	0.549	0.402	0.499	-
D10P	10 or more payment HCCs	0.505	0.897	0.373	1.056	0.548	0.893	-

NOTES:

1. The denominator is $9,365.50.
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Immune Disorders = HCC 47
   Cancer = HCCs 8-12
   Congestive Heart Failure = HCC 85
   Diabetes = HCCs 17-19
   Chronic Obstructive Pulmonary Disease = HCCs 110-112
   Renal = HCCs 134-138
   Cardiorespiratory Failure = HCCs 82-84
   Specified Heart Arrhythmias = HCC 96
   Substance Use Disorder = HCCs 54-56
   Psychiatric = HCCs 57-60
   Pressure Ulcer = HCCs 157-159
   Chronic Ulcer of Skin, except Pressure = HCC 161
   Bone/Joint/Muscle Infections/Necrosis = HCC 39
   Multiple Sclerosis = HCC 77
   Opportunistic Infections = HCC 6
   Sepsis = HCC 2
   Artificial Openings for Feeding or Elimination = HCC 188
   Aspiration and Specified Bacterial Pneumonias = HCC 114
   Schizophrenia = HCC 57
   Seizure Disorders and Convulsions = HCC 79

SOURCE: RTI International analysis of 2014-2015 Medicare 100% data and RTI International analysis of 2014-2015 Medicare 100% institutional sample.

Table VI-2. 2020 Alternative Payment Condition Count Model Relative Factors for Aged and Disabled New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.804	0.969	-	-
35-44 Years	0.947	1.202	-	-
45-54 Years	1.016	1.306	-	-
55-59 Years	1.017	1.307	-	-
60-64 Years	1.122	1.408	-	-
65 Years	0.520	0.993	1.122	1.462
66 Years	0.515	0.897	1.174	1.887
67 Years	0.544	0.920	1.174	1.887
68 Years	0.598	0.951	1.174	1.887
69 Years	0.600	0.951	1.174	1.887
70-74 Years	0.690	0.985	1.174	1.887
75-79 Years	0.860	1.134	1.174	1.887
80-84 Years	1.014	1.353	1.174	1.887
85-89 Years	1.293	1.536	1.293	1.887
90-94 Years	1.293	1.701	1.293	1.887
95 Years or Over	1.293	1.701	1.293	1.887
Male				
0-34 Years	0.442	0.734	-	-
35-44 Years	0.657	1.059	-	-
45-54 Years	0.864	1.353	-	-
55-59 Years	0.904	1.418	-	-
60-64 Years	0.921	1.551	-	-
65 Years	0.518	1.144	0.921	1.811
66 Years	0.533	1.094	1.071	2.199
67 Years	0.582	1.151	1.123	2.199
68 Years	0.626	1.202	1.123	2.199
69 Years	0.690	1.202	1.320	2.199
70-74 Years	0.786	1.298	1.408	2.199
75-79 Years	1.060	1.407	1.408	2.199
80-84 Years	1.247	1.555	1.408	2.199
85-89 Years	1.498	1.777	1.498	2.199
90-94 Years	1.498	1.777	1.498	2.199
95 Years or Over	1.498	1.777	1.498	2.199

NOTES:

1. The denominator is $9,365.50.
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2014-2015 100% Medicare data.

Table VI-3. 2020 Alternative Payment Condition Count Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.513	1.776	-	-
35-44 Years	1.513	1.776	-	-
45-54 Years	1.513	2.010	-	-
55-59 Years	1.619	2.095	-	-
60-64 Years	1.686	2.126	-	-
65 Years	0.999	1.375	1.810	2.183
66 Years	0.999	1.375	1.810	2.209
67 Years	1.070	1.483	1.834	2.213
68 Years	1.108	1.559	1.834	2.248
69 Years	1.164	1.576	1.834	2.336
70-74 Years	1.310	1.789	2.006	2.424
75-79 Years	1.516	1.980	2.112	2.562
80-84 Years	1.746	2.194	2.476	2.772
85-89 Years	1.971	2.490	2.476	2.772
90-94 Years	2.161	2.680	2.476	2.772
95 Years or Over	2.161	2.680	2.476	2.772
Male				
0-34 Years	1.276	1.533	-	-
35-44 Years	1.276	1.533	-	-
45-54 Years	1.498	1.854	-	-
55-59 Years	1.630	2.041	-	-
60-64 Years	1.673	2.167	-	-
65 Years	0.980	1.525	1.664	2.173
66 Years	0.980	1.525	1.667	2.173
67 Years	1.020	1.646	1.725	2.179
68 Years	1.082	1.646	1.740	2.179
69 Years	1.140	1.646	1.797	2.179
70-74 Years	1.345	1.967	1.935	2.419
75-79 Years	1.581	2.140	2.073	2.509
80-84 Years	1.832	2.272	2.349	2.805
85-89 Years	2.095	2.630	2.349	2.805
90-94 Years	2.351	2.630	2.349	2.805
95 Years or Over	2.351	2.630	2.349	2.805

NOTES:

1. The denominator is $9,365.50.
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2014-2015 100% Medicare data.

Table VI-4. Disease Hierarchies for the 2020 Alternative Payment Condition Count Model

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column…	…Then drop the Disease Group(s) listed in this column
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9, 10, 11, 12
9	Lung and Other Severe Cancers	10, 11, 12
10	Lymphoma and Other Cancers	11, 12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28, 29, 80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Substance Use with Psychotic Complications	55, 56
55	Substance Use Disorder, Moderate/Severe, or Substance Use with Complications	56
57	Schizophrenia	58, 59, 60
58	Reactive and Unspecified Psychosis	59, 60
59	Major Depressive, Bipolar, and Paranoid Disorders	60
70	Quadriplegia	71, 72, 103, 104, 169
71	Paraplegia	72, 104, 169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83, 84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87, 88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Intracranial Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107, 108, 161, 189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111, 112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135, 136, 137, 138
135	Acute Renal Failure	136, 137, 138
136	Chronic Kidney Disease, Stage 5	137, 138
137	Chronic Kidney Disease, Severe (Stage 4)	138
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158, 159, 161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159, 161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	161
166	Severe Head Injury	80, 167

How Payments are Made and Counts are Calculated with a Disease Hierarchy

EXAMPLE: If a beneficiary triggers Disease Groups 135 (Acute Renal Failure) and 136 (Chronic Kidney Disease, Stage 5), then DG 136 will be dropped. In other words, payment and payment HCC counts will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment and payment HCC counts will be based on DG 135 rather than DG 136.

SOURCE: RTI International.

Table VI-5. ESRD Model Continuing Enrollee Dialysis Relative Factors

Variable	Description Label	Relative Factors
Female		
0-34 Years		0.630
35-44 Years		0.577
45-54 Years		0.532
55-59 Years		0.545
60-64 Years		0.564
65-69 Years		0.647
70-74 Years		0.666
75-79 Years		0.670
80-84 Years		0.684
85-89 Years		0.684
90-94 Years		0.684
95 Years or Over		0.684
Male		
0-34 Years		0.537
35-44 Years		0.512
45-54 Years		0.487
55-59 Years		0.504
60-64 Years		0.507
65-69 Years		0.572
70-74 Years		0.622
75-79 Years		0.646
80-84 Years		0.664
85-89 Years		0.675
90-94 Years		0.675
95 Years or Over		0.675
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex		
Medicaid_Female_Aged		0.068
Medicaid_Female_NonAged (Age <65)		0.067
Medicaid_Male_Aged		0.124
Medicaid_Male_NonAged (Age <65)		0.092
Originally Disabled_Female[2]		–
Originally Disabled_Male[2]		–
Originally ESRD_Female[3]		-0.079
Originally ESRD_Male[3]		-0.050
Disease Coefficients		
HCC1	HIV/AIDS	0.156
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.083
HCC6	Opportunistic Infections	0.053
HCC8	Metastatic Cancer and Acute Leukemia	0.301

Variable	Description Label	Relative Factors
HCC9	Lung and Other Severe Cancers	0.172
HCC10	Lymphoma and Other Cancers	0.139
HCC11	Colorectal, Bladder, and Other Cancers	0.078
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.047
HCC17	Diabetes with Acute Complications	0.249
HCC18	Diabetes with Chronic Complications	0.093
HCC19	Diabetes without Complication	0.067
HCC21	Protein-Calorie Malnutrition	0.056
HCC22	Morbid Obesity	0.075
HCC23	Other Significant Endocrine and Metabolic Disorders	0.014
HCC27	End-Stage Liver Disease	0.208
HCC28	Cirrhosis of Liver	0.087
HCC29	Chronic Hepatitis	0.071
HCC33	Intestinal Obstruction/Perforation	0.073
HCC34	Chronic Pancreatitis	0.075
HCC35	Inflammatory Bowel Disease	0.054
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.063
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.073
HCC46	Severe Hematological Disorders	0.183
HCC47	Disorders of Immunity	0.099
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.060
HCC51	Dementia With Complications	0.099
HCC52	Dementia Without Complication	0.046
HCC54	Drug/Alcohol Psychosis	0.049
HCC55	Drug/Alcohol Dependence	0.049
HCC57	Schizophrenia	0.145
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.092
HCC70	Quadriplegia	0.279
HCC71	Paraplegia	0.204
HCC72	Spinal Cord Disorders/Injuries	0.104
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.120
HCC74	Cerebral Palsy	0.037
HCC75	Polyneuropathy	0.060
HCC76	Muscular Dystrophy	0.063
HCC77	Multiple Sclerosis	0.070
HCC78	Parkinson's and Huntington's Diseases	0.067
HCC79	Seizure Disorders and Convulsions	0.067
HCC80	Coma, Brain Compression/Anoxic Damage	0.044
HCC82	Respirator Dependence/Tracheostomy Status	0.246
HCC83	Respiratory Arrest	0.117
HCC84	Cardio-Respiratory Failure and Shock	0.045
HCC85	Congestive Heart Failure	0.084
HCC86	Acute Myocardial Infarction	0.134

Variable	Description Label	Relative Factors
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.118
HCC88	Angina Pectoris	0.049
HCC96	Specified Heart Arrhythmias	0.094
HCC99	Cerebral Hemorrhage	0.079
HCC100	Ischemic or Unspecified Stroke	0.079
HCC103	Hemiplegia/Hemiparesis	0.088
HCC104	Monoplegia, Other Paralytic Syndromes	0.078
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.327
HCC107	Vascular Disease with Complications	0.129
HCC108	Vascular Disease	0.067
HCC110	Cystic Fibrosis	0.073
HCC111	Chronic Obstructive Pulmonary Disease	0.073
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.067
HCC114	Aspiration and Specified Bacterial Pneumonias	0.064
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.014
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	–
HCC124	Exudative Macular Degeneration	0.056
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.282
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.164
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.149
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.149
HCC161	Chronic Ulcer of Skin, Except Pressure	0.121
HCC162	Severe Skin Burn or Condition	0.043
HCC166	Severe Head Injury	0.044
HCC167	Major Head Injury	0.017
HCC169	Vertebral Fractures without Spinal Cord Injury	0.066
HCC170	Hip Fracture/Dislocation	0.051
HCC173	Traumatic Amputations and Complications	0.043
HCC176	Complications of Specified Implanted Device or Graft	–
HCC186	Major Organ Transplant or Replacement Status	0.157
HCC188	Artificial Openings for Feeding or Elimination	0.080
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.092
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.038
CANCER_IMMUNE	Cancer*Immune Disorders	0.025
DIABETES_CHF	Diabetes*Congestive Heart Failure	–
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.022
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.025
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.074
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.115
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.160

Variable	Description Label	Relative Factors
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.135
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.125
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.303
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.040

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $80,612.96.
2. Originally Disabled indicates beneficiary originally entitled to Medicare for reasons of disability other than ESRD.
3. Originally ESRD indicates beneficiary originally entitled to Medicare due to ESRD. Beneficiaries who are Originally ESRD cannot be Originally Disabled.
4. In the "disease interactions," the variables are defined as follows:

   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Cancer = HCCs 8-12.
   Immune Disorders = HCC 47.
   Diabetes = HCCs 17-19.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table VI-6. ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.703	0.945	0.993	1.177
35-44 Years	0.703	0.912	0.993	1.177
45-54 Years	0.777	0.913	0.993	1.213
55-59 Years	0.813	0.930	0.993	1.213
60-64 Years	0.864	0.986	1.047	1.229
65-69 Years	0.994	1.148	1.096	1.249
70-74 Years	1.056	1.239	1.180	1.280
75-79 Years	1.056	1.239	1.223	1.320
80-84 Years	1.082	1.239	1.223	1.320
85 Years or Over	1.032	1.289	1.223	1.320
Male				
0-34 Years	0.620	0.795	0.888	1.104
35-44 Years	0.620	0.817	0.888	1.104
45-54 Years	0.673	0.842	0.888	1.127
55-59 Years	0.767	0.900	0.915	1.146
60-64 Years	0.803	0.944	0.915	1.206
65-69 Years	0.909	1.107	0.915	1.206
70-74 Years	0.999	1.225	1.082	1.307
75-79 Years	1.047	1.225	1.111	1.307
80-84 Years	1.041	1.225	1.111	1.307
85 Years or Over	1.029	1.316	1.111	1.307

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $80,612.96.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table VI-7. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	**Kidney Transplant** *Actual Dollars*	**Kidney Transplant Relative Risk Factor**
Month 1	9,606	$41,260.76	6.142
Months 2 and 3	18,651	$6,126.29	0.912
Total (Actual Months 1-3)		**$53,493.60**	

NOTES:

1. Kidney transplant is identified by MS-DRG 652.
2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.
3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator) x 12. The CMS ESRD Dialysis Denominator value used was $80,612.96.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table VI-8. ESRD Model Functioning Graft Relative Factors for Community Population

Variable	Description Label	Relative Factors
Functioning Graft Factors		
Aged <65, with duration since transplant of 4-9 months		2.174
Aged 65+, with duration since transplant of 4-9 months		2.562
Aged <65, with duration since transplant of 10 months or more		0.840
Aged 65+, with duration since transplant of 10 months or more		1.121
Female		
0-34 Years		0.196
35-44 Years		0.219
45-54 Years		0.256
55-59 Years		0.306
60-64 Years		0.360
65-69 Years		0.291
70-74 Years		0.350
75-79 Years		0.406
80-84 Years		0.480
85-89 Years		0.590
90-94 Years		0.724
95 Years or Over		0.737
Male		
0-34 Years		0.067
35-44 Years		0.076
45-54 Years		0.149
55-59 Years		0.226
60-64 Years		0.297
65-69 Years		0.274
70-74 Years		0.353
75-79 Years		0.425
80-84 Years		0.499
85-89 Years		0.625
90-94 Years		0.775
95 Years or Over		0.914
Medicaid and Originally Disabled Interactions with Age and Sex		
Medicaid_Female_Aged		0.275
Medicaid_Female_NonAged (Age <65)		0.137
Medicaid_Male_Aged		0.367
Medicaid_Male_NonAged (Age <65)		0.190
Originally Disabled_Female_Age ≥65		0.184
Originally Disabled_Male_Age ≥65		0.115
Disease Coefficients		
HCC1	HIV/AIDS	0.350
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.428
HCC6	Opportunistic Infections	0.426
HCC8	Metastatic Cancer and Acute Leukemia	2.627

Variable	Description Label	Relative Factors
HCC9	Lung and Other Severe Cancers	0.975
HCC10	Lymphoma and Other Cancers	0.668
HCC11	Colorectal, Bladder, and Other Cancers	0.298
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.156
HCC17	Diabetes with Acute Complications	0.243
HCC18	Diabetes with Chronic Complications	0.243
HCC19	Diabetes without Complication	0.094
HCC21	Protein-Calorie Malnutrition	0.593
HCC22	Morbid Obesity	0.278
HCC23	Other Significant Endocrine and Metabolic Disorders	0.234
HCC27	End-Stage Liver Disease	1.028
HCC28	Cirrhosis of Liver	0.384
HCC29	Chronic Hepatitis	0.243
HCC33	Intestinal Obstruction/Perforation	0.285
HCC34	Chronic Pancreatitis	0.282
HCC35	Inflammatory Bowel Disease	0.362
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.468
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.398
HCC46	Severe Hematological Disorders	1.325
HCC47	Disorders of Immunity	0.688
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.234
HCC51	Dementia With Complications	0.643
HCC52	Dementia Without Complication	0.328
HCC54	Drug/Alcohol Psychosis	0.352
HCC55	Drug/Alcohol Dependence	0.352
HCC57	Schizophrenia	0.442
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.260
HCC70	Quadriplegia	1.112
HCC71	Paraplegia	0.943
HCC72	Spinal Cord Disorders/Injuries	0.456
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.030
HCC74	Cerebral Palsy	–
HCC75	Polyneuropathy	0.284
HCC76	Muscular Dystrophy	0.544
HCC77	Multiple Sclerosis	0.546
HCC78	Parkinson's and Huntington's Diseases	0.583
HCC79	Seizure Disorders and Convulsions	0.221
HCC80	Coma, Brain Compression/Anoxic Damage	0.184
HCC82	Respirator Dependence/Tracheostomy Status	1.231
HCC83	Respiratory Arrest	0.540
HCC84	Cardio-Respiratory Failure and Shock	0.345
HCC85	Congestive Heart Failure	0.336
HCC86	Acute Myocardial Infarction	0.258

Variable	Description Label	Relative Factors
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.258
HCC88	Angina Pectoris	0.129
HCC96	Specified Heart Arrhythmias	0.303
HCC99	Cerebral Hemorrhage	0.252
HCC100	Ischemic or Unspecified Stroke	0.252
HCC103	Hemiplegia/Hemiparesis	0.467
HCC104	Monoplegia, Other Paralytic Syndromes	0.307
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.385
HCC107	Vascular Disease with Complications	0.431
HCC108	Vascular Disease	0.271
HCC110	Cystic Fibrosis	0.494
HCC111	Chronic Obstructive Pulmonary Disease	0.313
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.281
HCC114	Aspiration and Specified Bacterial Pneumonias	0.596
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.155
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.248
HCC124	Exudative Macular Degeneration	0.512
HCC134	Dialysis Status	–
HCC135	Acute Renal Failure	–
HCC136	Chronic Kidney Disease, Stage 5	–
HCC137	Chronic Kidney Disease, Severe (Stage 4)	–
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	–
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	–
HCC140	Unspecified Renal Failure	–
HCC141	Nephritis	–
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.492
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.285
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.955
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.799
HCC161	Chronic Ulcer of Skin, Except Pressure	0.503
HCC162	Severe Skin Burn or Condition	0.370
HCC166	Severe Head Injury	0.184
HCC167	Major Head Injury	0.184
HCC169	Vertebral Fractures without Spinal Cord Injury	0.456
HCC170	Hip Fracture/Dislocation	0.350
HCC173	Traumatic Amputations and Complications	0.290
HCC176	Complications of Specified Implanted Device or Graft	0.599
HCC186	Major Organ Transplant or Replacement Status	0.075
HCC188	Artificial Openings for Feeding or Elimination	0.643
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.654
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.133
CANCER_IMMUNE	Cancer*Immune Disorders	0.773
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.160

Variable	Description Label	Relative Factors
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.227
CHF_RENAL	Congestive Heart Failure*Renal Disease	–
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.453
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.561
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.534
NONAGED_HCC46	NonAged, Severe Hematological Disorders	2.791
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.549
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.066
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.746
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	–

NOTES:

1. The Denominator used to calculate the relative factors is $9,366.89.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.
4. In the "disease interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Cancer = HCCs 8-12.
   Immune Disorders = HCC 47.
   Diabetes = HCCs 17-19.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Renal Disease = HCCs 134-141.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table VI-9. ESRD Model Functioning Graft Relative Factors for Institutionalized Population

Variable	Description Label	Relative Factors
Functioning Graft Factors		
Aged <65, with duration since transplant of 4-9 months		2.600
Aged 65+, with duration since transplant of 4-9 months		3.064
Aged <65, with duration since transplant of 10 months or more		1.005
Aged 65+, with duration since transplant of 10 months or more		1.341
Female		
0-34 Years		1.015
35-44 Years		1.269
45-54 Years		1.187
55-59 Years		1.213
60-64 Years		1.216
65-69 Years		1.449
70-74 Years		1.340
75-79 Years		1.182
80-84 Years		1.030
85-89 Years		0.932
90-94 Years		0.778
95 Years or Over		0.579
Male		
0-34 Years		1.262
35-44 Years		1.143
45-54 Years		1.106
55-59 Years		1.162
60-64 Years		1.212
65-69 Years		1.516
70-74 Years		1.563
75-79 Years		1.549
80-84 Years		1.421
85-89 Years		1.317
90-94 Years		1.159
95 Years or Over		0.955
Medicaid and Originally Disabled		
Medicaid		0.089
Originally Disabled_Age ≥65		–
Disease Coefficients		
HCC1	HIV/AIDS	2.043
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.328
HCC6	Opportunistic Infections	0.679
HCC8	Metastatic Cancer and Acute Leukemia	1.542
HCC9	Lung and Other Severe Cancers	0.723
HCC10	Lymphoma and Other Cancers	0.539
HCC11	Colorectal, Bladder, and Other Cancers	0.340
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.232

Variable	Description Label	Relative Factors
HCC17	Diabetes with Acute Complications	0.446
HCC18	Diabetes with Chronic Complications	0.446
HCC19	Diabetes without Complication	0.197
HCC21	Protein-Calorie Malnutrition	0.302
HCC22	Morbid Obesity	0.513
HCC23	Other Significant Endocrine and Metabolic Disorders	0.429
HCC27	End-Stage Liver Disease	1.032
HCC28	Cirrhosis of Liver	0.572
HCC29	Chronic Hepatitis	0.572
HCC33	Intestinal Obstruction/Perforation	0.414
HCC34	Chronic Pancreatitis	0.505
HCC35	Inflammatory Bowel Disease	0.408
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.448
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.327
HCC46	Severe Hematological Disorders	0.916
HCC47	Disorders of Immunity	0.657
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.207
HCC51	Dementia With Complications	–
HCC52	Dementia Without Complication	–
HCC54	Drug/Alcohol Psychosis	0.134
HCC55	Drug/Alcohol Dependence	0.134
HCC57	Schizophrenia	0.260
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.260
HCC70	Quadriplegia	0.613
HCC71	Paraplegia	0.520
HCC72	Spinal Cord Disorders/Injuries	0.306
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.534
HCC74	Cerebral Palsy	–
HCC75	Polyneuropathy	0.387
HCC76	Muscular Dystrophy	0.354
HCC77	Multiple Sclerosis	–
HCC78	Parkinson's and Huntington's Diseases	0.168
HCC79	Seizure Disorders and Convulsions	0.078
HCC80	Coma, Brain Compression/Anoxic Damage	–
HCC82	Respirator Dependence/Tracheostomy Status	1.916
HCC83	Respiratory Arrest	0.557
HCC84	Cardio-Respiratory Failure and Shock	0.372
HCC85	Congestive Heart Failure	0.223
HCC86	Acute Myocardial Infarction	0.469
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.469
HCC88	Angina Pectoris	0.469
HCC96	Specified Heart Arrhythmias	0.295

Variable	Description Label	Relative Factors
HCC99	Cerebral Hemorrhage	0.126
HCC100	Ischemic or Unspecified Stroke	0.126
HCC103	Hemiplegia/Hemiparesis	–
HCC104	Monoplegia, Other Paralytic Syndromes	–
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.902
HCC107	Vascular Disease with Complications	0.359
HCC108	Vascular Disease	0.103
HCC110	Cystic Fibrosis	0.521
HCC111	Chronic Obstructive Pulmonary Disease	0.358
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.358
HCC114	Aspiration and Specified Bacterial Pneumonias	0.171
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.171
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.464
HCC124	Exudative Macular Degeneration	0.250
HCC134	Dialysis Status	–
HCC135	Acute Renal Failure	–
HCC136	Chronic Kidney Disease, Stage 5	–
HCC137	Chronic Kidney Disease, Severe (Stage 4)	–
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	–
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	–
HCC140	Unspecified Renal Failure	–
HCC141	Nephritis	–
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.158
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.452
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.269
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.269
HCC161	Chronic Ulcer of Skin, Except Pressure	0.269
HCC162	Severe Skin Burn or Condition	–
HCC166	Severe Head Injury	–
HCC167	Major Head Injury	–
HCC169	Vertebral Fractures without Spinal Cord Injury	0.284
HCC170	Hip Fracture/Dislocation	–
HCC173	Traumatic Amputations and Complications	0.072
HCC176	Complications of Specified Implanted Device or Graft	0.716
HCC186	Major Organ Transplant or Replacement Status	0.089
HCC188	Artificial Openings for Feeding or Elimination	0.577
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.406
Disease Interactions		

Variable	Description Label	Relative Factors
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.227
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.498
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.271
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.540
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.352
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.190
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.264
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.301
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.415
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.481
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.146
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.647
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.314
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.631
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.561
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.535
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.536
NONAGED_HCC6	NonAged, Opportunistic Infections	0.375

NOTES:

1. The Denominator used to calculate the relative factors is $9,366.89.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.
4. In the "Disease interactions" and "NonAged interactions," the variables are defined as follows:

   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Diabetes = HCCs 17-19.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Pressure Ulcer = HCCs 157-160.
   Artificial Openings for Feeding or Elimination = HCC 188.
   Aspiration and Specified Bacterial Pneumonias = HCC 114.
   Schizophrenia = HCC 57.
   Seizure Disorders and Convulsions = HCC 79.
   Chronic Ulcer of Skin, except Pressure = HCC 161.
   Bone/Joint/Muscle Infections/Necrosis = HCC 39.
   Multiple Sclerosis = HCC 77.
   Opportunistic Infections = HCC 6.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% institutional sample.

Table VI-10. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	3.695	3.899	–	–
35-44 Years	3.872	4.189	–	–
45-54 Years	3.957	4.317	–	–
55-59 Years	3.958	4.319	–	–
60-64 Years	4.103	4.444	–	–
65 Years	3.824	4.411	4.503	4.986
66 Years	3.818	4.291	4.503	4.986
67 Years	3.854	4.320	4.503	5.664
68 Years	3.920	4.358	4.772	5.664
69 Years	3.924	4.358	4.772	5.664
70-74 Years	4.035	4.401	4.772	5.664
75-79 Years	4.245	4.585	4.772	5.664
80-84 Years	4.437	4.857	4.772	5.664
85-89 Years	4.784	5.084	4.772	5.664
90-94 Years	4.784	5.290	4.772	5.664
95 Years or Over	4.784	5.290	4.772	5.664
Male				
0-34 Years	3.245	3.608	–	–
35-44 Years	3.512	4.011	–	–
45-54 Years	3.769	4.375	–	–
55-59 Years	3.818	4.456	–	–
60-64 Years	3.873	4.621	–	–
65 Years	3.821	4.599	4.204	5.426
66 Years	3.840	4.536	4.508	5.906
67 Years	3.901	4.607	4.572	5.906
68 Years	3.956	4.671	4.572	5.906
69 Years	4.035	4.671	4.915	5.906
70-74 Years	4.154	4.789	4.915	5.906
75-79 Years	4.493	4.925	4.915	5.906
80-84 Years	4.725	5.108	4.915	5.906
85-89 Years	5.010	5.383	4.915	5.906
90-94 Years	5.010	5.383	4.915	5.906
95 Years or Over	5.010	5.383	4.915	5.906

NOTES:

1. The relative factors are derived from the Graft New Enrollee model. The Denominator used to calculate the relative factors is $9,366.89.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table VI-11. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	2.040	2.244	–	–
35-44 Years	2.217	2.534	–	–
45-54 Years	2.302	2.662	–	–
55-59 Years	2.303	2.664	–	–
60-64 Years	2.448	2.789	–	–
65 Years	2.036	2.623	2.715	3.198
66 Years	2.030	2.503	2.715	3.198
67 Years	2.066	2.532	2.715	3.876
68 Years	2.132	2.570	2.984	3.876
69 Years	2.136	2.570	2.984	3.876
70-74 Years	2.247	2.613	2.984	3.876
75-79 Years	2.457	2.797	2.984	3.876
80-84 Years	2.649	3.069	2.984	3.876
85-89 Years	2.996	3.296	2.984	3.876
90-94 Years	2.996	3.502	2.984	3.876
95 Years or Over	2.996	3.502	2.984	3.876
Male				
0-34 Years	1.590	1.953	–	–
35-44 Years	1.857	2.356	–	–
45-54 Years	2.114	2.720	–	–
55-59 Years	2.163	2.801	–	–
60-64 Years	2.218	2.966	–	–
65 Years	2.033	2.811	2.416	3.638
66 Years	2.052	2.748	2.720	4.118
67 Years	2.113	2.819	2.784	4.118
68 Years	2.168	2.883	2.784	4.118
69 Years	2.247	2.883	3.127	4.118
70-74 Years	2.366	3.001	3.127	4.118
75-79 Years	2.705	3.137	3.127	4.118
80-84 Years	2.937	3.320	3.127	4.118
85-89 Years	3.222	3.595	3.127	4.118
90-94 Years	3.222	3.595	3.127	4.118
95 Years or Over	3.222	3.595	3.127	4.118

NOTES:

1. The relative factors are derived from the Graft New Enrollee model. The Denominator used to calculate the relative factors is $9,366.89.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table VI-12. List of Disease Hierarchies for the ESRD Model

DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	**If the Disease Group is Listed in this column…**	**…Then drop the HCC(s) listed in this column**
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9, 10, 11, 12
9	Lung and Other Severe Cancers	10, 11, 12
10	Lymphoma and Other Cancers	11, 12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28, 29, 80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71, 72, 103, 104, 169
71	Paraplegia	72, 104, 169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83, 84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87, 88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107, 108, 161, 189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111, 112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135, 136, 137, 138, 139, 140, 141
135	Acute Renal Failure	136, 137, 138, 139, 140, 141
136	Chronic Kidney Disease, Stage 5	137, 138, 139, 140, 141
137	Chronic Kidney Disease, Severe (Stage 4)	138, 139, 140, 141
138	Chronic Kidney Disease, Moderate (Stage 3)	139, 140, 141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140, 141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158, 159, 160, 161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159, 160, 161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160, 161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80, 167

How Payments are Made with a Disease Hierarchy
EXAMPLE: If a beneficiary triggers Disease Groups 8 (Metastatic Cancer and Acute Leukemia) and 9 (Lung and Other Severe Cancers), then DG 9 will be dropped. In other words, payment will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on DG 8 rather than DG 9.

SOURCE: RTI International.

Table VI-13. RxHCC Model (2014/2015) Relative Factors for Continuing Enrollees

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.303	-	0.440	1.809
35-44 Years		-	0.449	-	0.632	2.057
45-54 Years		-	0.555	-	0.733	1.735
55-59 Years		-	0.524	-	0.711	1.582
60-64 Years		-	0.482	-	0.645	1.441
65-69 Years		0.238	-	0.394	-	1.504
70-74 Years		0.238	-	0.369	-	1.377
75-79 Years		0.224	-	0.358	-	1.266
80-84 Years		0.205	-	0.319	-	1.170
85-89 Years		0.183	-	0.285	-	1.078
90-94 Years		0.138	-	0.231	-	0.959
95 Years or Over		0.076	-	0.143	-	0.766
Male						
0-34 Years		-	0.265	-	0.480	1.845
35-44 Years		-	0.388	-	0.607	1.839
45-54 Years		-	0.489	-	0.674	1.697
55-59 Years		-	0.524	-	0.681	1.510
60-64 Years		-	0.499	-	0.628	1.382
65-69 Years		0.261	-	0.371	-	1.333
70-74 Years		0.268	-	0.346	-	1.285
75-79 Years		0.244	-	0.346	-	1.210
80-84 Years		0.186	-	0.307	-	1.159
85-89 Years		0.141	-	0.290	-	1.087
90-94 Years		0.086	-	0.242	-	0.994
95 Years or Over		0.051	-	0.227	-	0.874
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.108	-	0.201	-	0.073
Originally Disabled_Male		-	-	0.136	-	0.073
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	3.067	3.700	3.825	4.172	2.604
RXHCC5	Opportunistic Infections	0.268	0.122	0.177	0.164	0.182
RXHCC15	Chronic Myeloid Leukemia	7.278	7.417	8.231	10.015	4.951
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	3.876	4.091	3.263	3.703	1.102
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.727	1.677	1.618	1.605	0.584
RXHCC18	Lung, Kidney, and Other Cancers	0.287	0.255	0.328	0.319	0.070
RXHCC19	Breast and Other Cancers and Tumors	0.096	0.085	0.079	0.116	0.070
RXHCC30	Diabetes with Complications	0.408	0.448	0.507	0.702	0.476
RXHCC31	Diabetes without Complication	0.270	0.256	0.320	0.394	0.322
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.970	10.502	3.147	10.565	0.476

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.099	0.205	0.061	0.231	0.087
RXHCC42	Thyroid Disorders	0.101	0.182	0.100	0.167	0.078
RXHCC43	Morbid Obesity	0.055	-	0.075	0.069	0.174
RXHCC45	Disorders of Lipoid Metabolism	0.037	-	0.069	0.089	0.053
RXHCC54	Chronic Viral Hepatitis C	3.165	3.642	2.954	2.979	0.955
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.534	0.329	0.868	0.539	0.373
RXHCC65	Chronic Pancreatitis	0.253	0.192	0.160	0.206	0.174
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.104	0.192	0.117	0.206	0.119
RXHCC67	Inflammatory Bowel Disease	0.512	0.459	0.463	0.839	0.212
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.078	0.065	0.143	0.171	0.078
RXHCC80	Aseptic Necrosis of Bone	0.179	0.260	0.110	0.146	0.116
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.761	0.737	1.309	2.087	0.665
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.381	0.418	0.489	0.814	0.189
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.217	0.347	0.242	0.357	0.172
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.052	0.157	0.122	0.206	-
RXHCC95	Sickle Cell Anemia	0.090	0.270	0.048	0.797	0.349
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.945	1.121	0.780	0.717	0.549
RXHCC97	Immune Disorders	0.551	0.524	0.493	0.459	0.350
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.090	0.164	0.048	0.222	0.046
RXHCC111	Alzheimer`s Disease	0.468	0.238	0.179	0.035	-
RXHCC112	Dementia, Except Alzheimer`s Disease	0.195	0.107	0.041	-	-
RXHCC130	Schizophrenia	0.280	0.311	0.409	0.708	0.203
RXHCC131	Bipolar Disorders	0.269	0.296	0.287	0.449	0.203
RXHCC132	Major Depression	0.132	0.222	0.145	0.314	0.170
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.132	0.191	0.145	0.314	0.111
RXHCC134	Depression	0.132	0.179	0.139	0.208	0.111
RXHCC135	Anxiety Disorders	0.053	0.118	0.086	0.173	0.111
RXHCC145	Autism	0.132	0.191	0.372	0.378	0.111
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	-	0.191	0.372	0.338	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	-	-	0.243	0.160	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.097	0.033	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.370	0.584	0.392	0.580	0.183
RXHCC157	Spinal Cord Disorders	0.117	0.099	0.095	0.057	0.056
RXHCC159	Inflammatory and Toxic Neuropathy	0.173	0.392	0.171	0.334	0.081
RXHCC160	Multiple Sclerosis	2.297	3.846	2.034	4.112	0.980

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC161	Parkinson's and Huntington's Diseases	0.501	0.702	0.319	0.440	0.228
RXHCC163	Intractable Epilepsy	0.298	0.546	0.315	1.042	0.094
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.126	0.082	0.049	0.150	-
RXHCC165	Convulsions	0.056	0.029	0.030	0.069	-
RXHCC166	Migraine Headaches	0.143	0.221	0.129	0.142	0.111
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.136	0.304	0.159	0.214	0.198
RXHCC185	Primary Pulmonary Hypertension	0.731	2.179	0.639	1.819	0.259
RXHCC186	Congestive Heart Failure	0.167	0.148	0.227	0.145	0.140
RXHCC187	Hypertension	0.124	0.073	0.191	0.109	0.060
RXHCC188	Coronary Artery Disease	0.123	0.012	0.143	-	0.012
RXHCC193	Atrial Arrhythmias	0.280	0.100	0.142	0.010	0.089
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.043	-	0.040	-	-
RXHCC207	Spastic Hemiplegia	0.190	0.151	0.033	0.162	-
RXHCC215	Venous Thromboembolism	0.148	0.197	0.096	0.108	0.050
RXHCC216	Peripheral Vascular Disease	-	-	0.021	-	-
RXHCC225	Cystic Fibrosis	0.729	5.452	0.368	5.320	1.168
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.325	0.140	0.368	0.260	0.204
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.325	0.140	0.176	0.260	0.041
RXHCC241	Diabetic Retinopathy	0.286	0.211	0.228	0.151	0.160
RXHCC243	Open-Angle Glaucoma	0.277	0.230	0.338	0.274	0.231
RXHCC260	Kidney Transplant Status	0.341	0.158	0.384	0.423	0.189
RXHCC261	Dialysis Status	0.227	0.460	0.490	0.939	0.411
RXHCC262	Chronic Kidney Disease Stage 5	0.092	0.115	0.085	0.043	0.056
RXHCC263	Chronic Kidney Disease Stage 4	0.092	0.115	0.085	0.043	0.056
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.161	0.171	0.103	0.100	0.056
RXHCC314	Pemphigus	0.365	0.662	0.197	0.124	0.049
RXHCC316	Psoriasis, Except with Arthropathy	0.206	0.249	0.413	0.728	0.282
RXHCC355	Narcolepsy and Cataplexy	0.829	1.358	0.656	1.365	0.253
RXHCC395	Lung Transplant Status	1.427	0.829	0.996	0.871	0.878
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.064	0.829	0.996	0.871	0.189
RXHCC397	Pancreas Transplant Status	0.002	0.158	0.384	0.235	0.189
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	0.916
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.278
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.277
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.184
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.226
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.113
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.192
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.341

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.250

NOTE: The Part D Denominator used to calculate relative factors is $1,036.61. This Part D Denominator is based on the combined PDP and MA-PD populations.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table VI-14. RxHCC Model (2014/2015) Relative Factors for New Enrollees, Non-Low Income

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.701	1.020	-	-
35-44 Years	1.212	1.232	-	-
45-54 Years	1.312	1.560	-	-
55-59 Years	1.253	1.715	-	-
60-64 Years	1.240	1.914	-	-
65 Years	0.528	1.923	1.136	1.923
66 Years	0.577	1.923	1.161	1.923
67 Years	0.590	1.923	1.161	1.923
68 Years	0.608	1.923	1.161	1.923
69 Years	0.633	1.923	1.161	1.923
70-74 Years	0.661	1.923	1.048	1.923
75-79 Years	0.680	1.923	0.810	1.923
80-84 Years	0.615	1.923	0.615	1.923
85-89 Years	0.607	1.923	0.607	1.923
90-94 Years	0.354	1.923	0.354	1.923
95 Years or Over	0.354	1.923	0.354	1.923
Male				
0-34 Years	0.465	0.819	-	-
35-44 Years	0.850	1.247	-	-
45-54 Years	1.145	1.560	-	-
55-59 Years	1.216	1.782	-	-
60-64 Years	1.185	2.087	-	-
65 Years	0.587	1.936	1.019	1.936
66 Years	0.632	1.936	1.014	1.936
67 Years	0.648	1.936	1.014	1.936
68 Years	0.677	1.936	1.014	1.936
69 Years	0.698	1.936	1.014	1.936
70-74 Years	0.741	1.936	0.942	1.936
75-79 Years	0.768	1.936	0.768	1.936
80-84 Years	0.696	1.936	0.696	1.936
85-89 Years	0.653	1.936	0.653	1.936
90-94 Years	0.307	1.936	0.307	1.936
95 Years or Over	0.307	1.936	0.307	1.936

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,036.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table VI-15. RxHCC Model (2014/2015) Relative Factors for New Enrollees, Low Income

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	1.036	2.174	-	-
35-44 Years	1.548	2.223	-	-
45-54 Years	1.601	2.310	-	-
55-59 Years	1.482	2.428	-	-
60-64 Years	1.391	2.259	-	-
65 Years	0.911	2.210	1.263	2.210
66 Years	0.623	2.210	0.846	2.210
67 Years	0.594	2.210	0.846	2.210
68 Years	0.607	2.210	0.846	2.210
69 Years	0.607	2.210	0.846	2.210
70-74 Years	0.607	2.210	0.796	2.210
75-79 Years	0.671	2.210	0.671	2.210
80-84 Years	0.671	2.210	0.671	2.210
85-89 Years	0.671	2.210	0.671	2.210
90-94 Years	0.570	2.210	0.570	2.210
95 Years or Over	0.570	2.210	0.570	2.210
Male				
0-34 Years	0.892	2.273	-	-
35-44 Years	1.278	2.277	-	-
45-54 Years	1.478	2.357	-	-
55-59 Years	1.391	2.213	-	-
60-64 Years	1.303	2.165	-	-
65 Years	0.906	2.056	1.157	2.056
66 Years	0.585	2.056	0.750	2.056
67 Years	0.560	2.056	0.750	2.056
68 Years	0.506	2.056	0.750	2.056
69 Years	0.526	2.056	0.750	2.056
70-74 Years	0.533	2.056	0.598	2.056
75-79 Years	0.552	2.056	0.552	2.056
80-84 Years	0.552	2.056	0.552	2.056
85-89 Years	0.552	2.056	0.552	2.056
90-94 Years	0.416	2.056	0.416	2.056
95 Years or Over	0.416	2.056	0.416	2.056

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,036.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table VI-16. RxHCC Model (2014/2015) Relative Factors for New Enrollees, Institutional

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.812	2.825
35-44 Years	2.812	2.825
45-54 Years	2.500	2.825
55-59 Years	2.500	2.825
60-64 Years	2.140	2.825
65 Years	2.228	2.825
66 Years	1.952	2.825
67 Years	1.952	2.825
68 Years	1.952	2.825
69 Years	1.952	2.825
70-74 Years	1.819	2.825
75-79 Years	1.586	2.825
80-84 Years	1.443	2.825
85-89 Years	1.383	2.825
90-94 Years	1.101	2.825
95 Years or Over	1.101	2.825
Male		
0-34 Years	2.446	2.842
35-44 Years	2.632	2.842
45-54 Years	2.400	2.842
55-59 Years	2.189	2.842
60-64 Years	2.134	2.842
65 Years	2.086	2.842
66 Years	1.814	2.842
67 Years	1.814	2.842
68 Years	1.814	2.842
69 Years	1.814	2.842
70-74 Years	1.715	2.842
75-79 Years	1.721	2.842
80-84 Years	1.524	2.842
85-89 Years	1.359	2.842
90-94 Years	1.359	2.842
95 Years or Over	1.359	2.842

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,036.61. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table VI-17. List of Disease Hierarchies for RxHCC Model (2014/2015)

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is listed in this column…	…Then drop the RxHCC(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
15	Chronic Myeloid Leukemia	16, 17, 18, 19, 96, 98
16	Multiple Myeloma and Other Neoplastic Disorders	17, 18, 19, 96, 98
17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	18, 19
18	Lung, Kidney, and Other Cancers	19
30	Diabetes with Complications	31
54	Chronic Viral Hepatitis C	55
65	Chronic Pancreatitis	66
82	Psoriatic Arthropathy and Systemic Sclerosis	83, 84, 316
83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	84
95	Sickle Cell Anemia	98
96	Myelodysplastic Syndromes and Myelofibrosis	98
111	Alzheimer's Disease	112
130	Schizophrenia	131, 132, 133, 134, 135, 145, 146, 147, 148
131	Bipolar Disorders	132, 133, 134, 135
132	Major Depression	133, 134, 135
133	Specified Anxiety, Personality, and Behavior Disorders	134, 135
134	Depression	135
145	Autism	133, 134, 135, 146, 147, 148
146	Profound or Severe Intellectual Disability/Developmental Disorder	147, 148
147	Moderate Intellectual Disability/Developmental Disorder	148
163	Intractable Epilepsy	164, 165
164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	165
185	Primary Pulmonary Hypertension	186, 187
186	Congestive Heart Failure	187
225	Cystic Fibrosis	226, 227
226	Chronic Obstructive Pulmonary Disease and Asthma	227
260	Kidney Transplant Status	261, 262, 263, 397
261	Dialysis Status	262, 263
262	Chronic Kidney Disease Stage 5	263
395	Lung Transplant Status	396, 397
396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	397

How Payments are Made with a Disease Hierarchy

EXAMPLE: If a beneficiary triggers Disease Groups 163 (Intractable Epilepsy) and 164 (Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy), then DG 164 will be dropped. In other words, payment will always be associated with the DG in column 1 if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on DG 163 rather than DG 164.

SOURCE: RTI International.

Attachment VII. 2020 Final Call Letter

CY 2020 Call Letter
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How to Use This Call Letter

The CY 2020 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs), Part D sponsors, and Medicare-Medicaid Plans (MMPs) need to take into consideration in preparing their 2020 bids.

CMS has designed the policies contained in this Call Letter to improve the overall management of the Medicare Advantage and Prescription Drug programs. Through these policies, CMS aims to expand plan flexibilities so that patients have a range of health plan options and are empowered to choose the option that best meets their individual health care needs. The policies in the Call Letter also reflect CMS efforts to increase transparency in our decision-making and promote innovation.

If you have questions concerning this Call Letter, please contact: Cali Diehl at Cali.Diehl@cms.hhs.gov (Part C issues), Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues), or mmcocapsmodel@cms.hhs.gov (MMP issues).

Section I – Parts C and D

Annual Calendar

Below is a calendar listing of key dates and timelines for operational activities that pertain to Medicare Advantage (MA) plans, Medicare Advantage-Prescription Drug (MA-PD) plans, Prescription Drug Plans (PDPs), Medicare-Medicaid Plans (MMPs), and cost-based plans. The calendar provides important operational dates for all organizations such as the date bids are due to CMS, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings.

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
January 1 – March 31, 2019	Annual Medicare Advantage Open Enrollment Period.	✓			
January 9, 2019	Contract Year (CY) 2020 Initial and Service Area Expansion Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion Applications are released.	✓	✓	✓	✓
January 9, 2019	Model of Care (MOC) renewal submission period begins for D-SNPs and I-SNPs with Model of Care (MOC) approvals ending 12/31/2019.	✓			
January 2019	Industry training for CY 2020 MOC submissions.	✓			
January 10, 2019	Annual MOC submission period begins for C-SNPs	✓			
January 2019	Industry training on CY 2020 Applications.	✓	✓	✓	✓
February 13, 2019	CY 2020 Initial and Service Area Expansion Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion Applications are due in the Health Plan Management System (HPMS) by 8pm EST.	✓	✓	✓	✓
February 13, 2019	MOC renewal submissions for D-SNPs and I-SNPs with MOC approvals ending 12/31/2019 due in HPMS by 8pm EST.	✓			
February 13, 2019	Annual MOC submissions for C-SNPs due in HPMS by 8pm EST.	✓			
Late February, 2019	Submission of meaningful use HITECH attestation for qualifying MA EGWP and MA-affiliated hospitals.	✓			
February 2019	CMS releases instructional memo concerning updates to Parent Organization designations in HPMS.	✓	✓	✓	✓
March 16, 2019	Parent Organization designation updates from MAOs and sponsors due to CMS (instructional memo released in February 2019).	✓	✓	✓	✓
Mid-Late March, 2019	Release of CY 2020 Formulary Reference File (FRF).	✓	✓	✓	✓
March 30, 2019	Release of the Fiscal Soundness Module in HPMS.	✓	✓	✓	✓

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
March/April, 2019	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2020.	✓	✓	✓	
Early/Mid-April, 2019	CY 2020 Out-Of-Pocket Cost (OOPC) model and OOPC estimates available for download to MAOs, 1876 cost plans submitting MA conversion bids, and Part D sponsors to assist in meeting meaningful difference (if applicable) and Total Beneficiary Cost (TBC) requirements prior to bid submission.	✓	✓	✓	
Early April, 2019	Release of guidance regarding CY 2020 renewal options, including crosswalks.	✓	✓		
April 1, 2019	Release of the 2020 Final Rate Announcement of MA Capitation Rates and MA and Part D Payment Policies, including the CY 2020 Call Letter.	✓	✓	✓	✓
April 2019	Conference call with industry on the CY 2020 Rate Announcement and Call Letter.	✓	✓	✓	✓
April 5, 2019	Release of the CY 2020 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓	✓
April 10, 2019	Deadline for MAOs and cost plans to submit full contract consolidation requests for CY 2020.	✓		✓	
Mid-April, 2019	Release of CY 2020 MA Bid Review and Operational Guidance.	✓		✓	
April 22, 2019	Release of the CY 2020 Medication Therapy Management (MTM) Program Submission in HPMS (11:59 p.m. PDT).		✓		✓
Mid-April, 2019	CMS to release industry guidance on CY 2020 Part D Formulary and Benefit Submission.	✓	✓	✓	✓
Late April, 2019	Release of CY 2020 TBC data.	✓			
May 6, 2019	Deadline for submission of CY 2020 MTM Programs from all sponsors offering Part D, including Medicare-Medicaid Plans (except those participating in the Enhanced MTM Model test) (11:59 p.m. PDT).		✓		✓
May 2019	Release of final CY 2020 ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for all organizations.	✓	✓	✓	
Early May 2019	Deadline for MA, MA-PD and PDP plans to notify CMS of their intention to non-renew a county (ies) or region(s) for individuals, but continue the county (ies) or region(s) for "800 series" EGWP members, to convert to offering employer-only contracts, or to reduce service areas at the contract level.	✓	✓	✓	
Early May 2019	CMMI Model Participant Provisional Approvals (VBID and Part D Payment Modernization Models)	✓	✓		
May 1, 2019	Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast.	✓	✓	✓	✓

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
May 4, 2019	Release of the CY 2020 Bid Upload Functionality in HPMS.	✓	✓	✓	✓
May 20, 2019	Deadline for submission of CY 2020 MTM Program attestations in HPMS (11:59 pm PDT).		✓		✓
May-July, 2019	Release of final state-specific MMP CY 2020 models: ANOC/EOC (Member Handbook), Summary of Benefits, Formulary, Provider and Pharmacy Directory, Member ID Card, and other MMP-specific models.				✓
May 14, 2019	Release of CY 2020 Formulary Submission Module in HPMS.	✓	✓	✓	✓
May 17, 2019	Release of CY2020 Actuarial Certification Module in HPMS.	✓	✓	✓	
Mid-Late May, 2019	Release of CY 2020 Formulary Reference File Update.	✓	✓	✓	✓
May 25, 2019	Submission period begins for Plans/Part D sponsors to upload agent/broker compensation information in HPMS.	✓	✓	✓	✓
Late May 2019	Qualification determinations provided to CY 2020 applicants for new contracts or service area expansions.	✓	✓	✓	✓
May 31, 2019	Release of the 2018 DIR Submission Module in HPMS.	✓	✓	✓	✓
June 1, 2019	Submission period begins Release of the CY 2020 Marketing Module in HPMS for Plans/Part D sponsors begin to submit upload 2020 marketing materials in CY 2020 Marketing Module.	✓	✓	✓	✓
June 3, 2019	Deadline for submission of CY 2020 bids (including Service Area Verification) for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2020 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2020 Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Deadline for submission of a CY 2020 contract non-renewal, service area reduction via HPMS from MA plans, MA-PD plans, MMPs, PDPs and Medicare cost-based contractors and cost- based sponsors to Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PD plan benefit package (i.e., Plan 01, Plan 02) for CY 2020.	✓	✓	✓	✓ *Non-bid related items only*
Early June to Late August 2019	Completion of CMS's CY 2020 bid review and approval, to include pricing, plan benefit packages, and formularies. Deadline for Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications.	✓	✓	✓	✓

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
June 2019	CMS conducts Network Adequacy Reviews	✓		✓	
June 2019	Initial submission period begins for Plans/Part D sponsors to request crosswalk exceptions.	✓	✓	✓	
June 7, 2019	Deadline for submission of CY 2020 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS (11:59 a.m. EDT).		✓		✓
June 7, 2019	Deadline for submission of Value-Based Insurance Design (VBID) file (Only applicable to MA plans that have been preapproved for Part D VBID benefits) (11:59 p.m. EDT).	✓			
June 7, 2019	Deadline for submission of Additional Demonstration Drug (ADD) file (MMPs only) (11:59 p.m. EDT).				✓
Mid to late June 2019	Release of the CY 2020 Medicare Communications and Marketing Guidelines in HPMS.	✓	✓	✓	✓
Late June 2019	Acknowledgement letter sent to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓	✓
July-August, 2019	Release of state-specific marketing guidance for MMPs.				✓
Early July 2019	Submission period for 2020 Medicare Plan Finder pricing tests.	✓	✓	✓	✓
Early July 2019	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS.	✓			
Early July 2019	Deadline for D-SNPs to submit their Fully Integrated Dual Eligible (FIDE) SNP Matrix for review and qualification.	✓			
July 5, 2019	Deadline for plans to submit non-model Low Income Subsidy (LIS) riders for review.	✓			
Mid July 2019	Release of CY 2020 FRF Update in advance of the Limited Formulary Update Window.	✓	✓	✓	✓
Mid-Late July 2019	CY 2020 Limited Formulary Update Window.	✓	✓	✓	✓
Late July 2019	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓	✓
July 2019	Second submission period begins for Plans/Part D sponsors to request crosswalk exceptions.	✓	✓	✓	
Late July 2019	Release of the CY 2020 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, the Medicare Advantage regional PPO benchmarks, and the de minimis amount.	✓	✓	✓	✓
Late July / Early August 2019	Rebate reallocation period begins after release of bid amounts.	✓	✓	✓	

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
No Later Than July 29, 2019	Deadline for informing currently contracted organizations of CMS's decision to not renew a contract for 2020.	✓	✓	✓	
August 1, 2019	Deadline to submit model LIS riders in HPMS.	✓	✓	✓	
August 17, 2019	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 16-20, 2019	Window for organizations to review 2020 Medicare & You Handbook data prior to printing (not applicable to EGWPs).	✓	✓	✓	✓
August 22-24, 2019	First CY 2020 Medicare Plan Finder (MPF) Preview and OOPC Preview in HPMS.	✓	✓	✓	✓ *MPF only*
August 31, 2019	CY 2020 MTM Program Annual Review completed.		✓		✓
Late August 2019	CY 2020 Contracting Materials countersigned in HPMS.	✓	✓	✓	
Late August / Early September 2019	Deadline after which organizations with pending administrative appeals of Initial or Service Area Expansion applications may be suppressed from Medicare & You Handbook and Medicare Plan Finder.	✓	✓	✓	
End of August/Early September 2019	Plan preview periods of Part C & D Star Ratings in HPMS.	✓	✓	✓	
Early September 2019	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
Mid-September 2019	All CY 2020 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓	
September 4-7, 2019	Second CY 2020 MPF Preview and OOPC Preview in HPMS.	✓	✓	✓	✓ *MPF only*
September 16 - 30, 2019	CMS mails the 2020 Medicare & You handbook to beneficiaries.	✓	✓	✓	✓
Late September 2019	CMS notifies D-SNPs that requested review for FIDE SNP determination whether they meet required qualifications.	✓			
Late September 2019	Deadline for Part D sponsors, cost-based plans, and MA and MA-PD organizations to request a plan correction to the PBP via HPMS.	✓	✓	✓	
September 30, 2019	Deadline for organizations to provide the following documents to current enrollees: • Standardized Annual Notice of Change (ANOC) for all MA, MA-PD, MMP, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • LIS rider	✓	✓	✓	✓

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
October 1, 2019	Date organizations may begin marketing their CY 2020 plans. Organizations may market both CY 2019 and CY 2020 simultaneously, but must clearly indicate which plan year is being discussed.	✓	✓	✓	✓
October 1, 2019	Tentative date by which plan and drug benefit data for CY 2020 is displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓	✓
October 2, 2019	Date by which the final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, MMP and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, MMPs and cost-based organizations may not market to enrollees of non-renewing plans until after October 2, 2019.	✓	✓	✓	✓
October 9, 2019	Part C & D Star Ratings go live on medicare.gov **on or around** October 9, 2019.	✓	✓	✓	
October 15, 2019	Deadline for organizations to provide the following documents (or notification, if permitted) to current enrollees: • Evidence of Coverage (EOC) for all MA, MA-PD, MMP, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • Abridged or comprehensive formularies • Provider/Pharmacy directories	✓	✓	✓	✓
October 15, 2019	Part D sponsors must post prior authorization and Part D step therapy criteria on their websites for CY 2020.		✓		✓
October 15, 2019	CY 2020 Annual Election Period begins. All MA organizations/PDP sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓		✓
Mid October 2019	Release of the online CY 2021 Notice of Intent to Apply (NOIA) for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs).	✓	✓	✓	✓
November 12, 2019	Deadline for submission of NOIA for CY 2021 MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November 2019	First display of Medicare Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval.	✓	✓	✓	✓
Late November 2019	Part C & D display measures data are posted in HPMS for plan preview.	✓	✓	✓	
December 1, 2019	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	

2020*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
December 7, 2019	CY 2020 Annual Election Period ends.	✓	✓		✓
Mid December 2019	Part C & D display measures data is updated on cms.gov.	✓	✓	✓	
December 31, 2019	Deadline for submitting Annual Chronic Care Improvement Program (CCIP) attestations in HPMS, as per §422.152 of Title 42 of the CFR.	✓			✓
2020					
January 1, 2020	Plan Benefit Period Begins.	✓	✓	✓	✓
January 1 – March 31, 2020	Annual Medicare Advantage Open Enrollment Period.	✓			
January 2020	Release of CY 2021 MAO/MA-PD/MMP/PDP/EGWP applications.	✓	✓		✓
January 1, 2020	Industry training on CY 2021 applications.	✓	✓	✓	✓
February 2020	CY 2021 Initial and Service Area Expansion Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion Applications are due.	✓	✓	✓	✓
June 1, 2020	CY 2021 Deadline for bid and formulary submission.	✓	✓	✓	✓ *Non-bid related items only*

Enhancements to the 2020 Star Ratings and Future Measurement Concepts

CMS publishes the Part C and D Star Ratings each year to measure the quality of and reflect the experiences of beneficiaries in Medicare Advantage (MA) and Prescription Drug Plans (PDPs or Part D plans), assist beneficiaries in finding the best plan, and determine MA Quality Bonus Payments. The Star Ratings support CMS's efforts to make the patient the focus in all of our programs. As part of this effort, it is key to empower patients to work with their health care providers to make health care decisions that are best for them. An important component of this effort is to provide Medicare beneficiaries and their family and caregivers with meaningful information about quality and costs to empower them to be active health care consumers engaged in their care. Furthermore, it is critical that the information we provide to Medicare beneficiaries is complete, accurate, and reliable.

CMS regularly reviews the measures and methodology (used to generate the ratings) to incentivize plans and provide information that is a true reflection of plan performance and enrollee experience. We remain cognizant of the unique challenges of serving traditionally underserved subsets of the population, such as beneficiaries with disabilities or who are dually eligible for Medicare and Medicaid. In addition to conducting our own research, CMS stays abreast of the related research and listens carefully to concerns about the Star Ratings. CMS works in collaboration with beneficiaries, stakeholders, measure developers, researchers, and other HHS collaborators to improve the Star Ratings. A Technical Expert Panel (TEP), comprised of representatives across various stakeholder groups, was convened on May 31, 2018 to provide feedback to CMS's Star Ratings contractor (currently RAND Corporation) on the Star Ratings framework, topic areas, methodology, and operational measures. Additional information about the TEP can be found at http://www.rand.org/star-ratings-analyses.

We proposed enhancements to the 2020 Star Ratings and solicited feedback on possible future measure updates and concepts. We appreciate the feedback we received on the draft CY 2020 Call Letter. Except as noted below, the methodology and measures used to calculate the 2020 Star Ratings will remain the same as for the 2019 Star Ratings. For reference, the list of measures and a description of the methodology for the 2019 Star Ratings are included in the Technical Notes available on the CMS webpage: http://go.cms.gov/partcanddstarratings.

As part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program, CMS codified the methodology for the Part C and D Star Ratings program in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (CMS-4182-F) (hereafter referred to as the "CY 2019 Final Rule") published in April 2018. The CY 2019 Final Rule includes the methodology for the 2021 Star Ratings. Historically, the Part C and D Star Ratings methodology was adopted and updated through the Part C and D Call Letter, with additional guidance issued in annual Technical Notes. Starting with the 2021 Star Ratings, any

changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes will be proposed and finalized through rulemaking. On November 1, 2018 CMS published in the Federal Register the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (83 FR 55021) ("CY 2020 Proposed Rule") which proposed changes to the methodology for calculating the ratings, beginning with the 2022 Star Ratings. This Call Letter focuses on the methodology for the 2020 Star Ratings and solicits input on measures and measure topics for future Star Ratings years.

Reminders for 2020 Star Ratings

CMS assigns stars for each numeric measure score by applying one of two methods: clustering or relative distribution with significance testing. Each method is described in detail in the Technical Notes. Relative distribution with significance testing is applied to determine valid star cut points for Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. Clustering is applied to other Star Ratings measures. The cut points to determine star assignments for all measures and case-mix coefficients for the CAHPS survey and Health Outcomes Survey (HOS) will be updated for 2020 Star Ratings using the most current data available.

As announced in previous years, we will review data quality across all measures, variation among organizations and sponsors, and measures' accuracy and validity before making a final determination about inclusion of measures in the Star Ratings.

We provide various datasets and reports to plan sponsors throughout the year. Part C and D sponsors should regularly review their underlying measure data that are the basis for the Part C and D Star Ratings and immediately alert CMS if errors or anomalies are identified so any issues can be resolved prior to the first plan preview period. For example, any requests for changes to the Independent Review Entity (IRE) data must be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (e.g., changes to 2018 IRE data must be made by June 30, 2019 for the 2020 Star Ratings). CMS has worked with MAXIMUS, the IRE, to add a late indicator on the website for Part C Appeals data to make it easier for plans to monitor the timeliness of their cases. This update will further allow plans to request adjustments to their Part C appeals, if necessary, in a timely manner. Please note reopenings are not taken into account under this deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measures, if a reopening occurs and is decided prior to May 1st, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1st, the original reconsidered determination is used. Plans should be aware that when underlying measure data are not reviewed timely and concerns are brought to CMS late in the process, operational constraints limit our ability to review and potentially adjust Star Ratings prior to the public release in early October. Any concerns with underlying measure data brought to our attention after the first plan

preview will be reviewed, however any adjustments needed to a contract's Star Ratings may be made after the initial public release.

Similarly, for complaints data, any requests for adjustments must be made in the Complaints Tracking Module (CTM) per the CTM Standard Operating Procedure (SOP) by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (e.g., changes to 2018 complaint data must be made by June 30, 2019 for the 2020 Star Ratings).

Measure Updates for 2020 Star Ratings

Medication Adherence (ADH) for Cholesterol (Statins) (Part D). The Pharmacy Quality Alliance (PQA) updated this measure for the 2018 measurement year to exclude beneficiaries with end-stage renal disease (ESRD). In the final CY 2019 Call Letter, we adopted our proposal to apply this exclusion to the 2020 Star Ratings (which are calculated based on 2018 data), in the same manner that the ESRD exclusion is currently applied to the Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Statin Use in Persons with Diabetes measures. Comments to the draft 2020 Call Letter offered additional support.

Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D). The PQA updated this measure for 2018 to include a new denominator rule in order to accurately account for all CMRs received. We adopted this change in the final CY 2019 Call Letter, and most commenters in response to the draft 2020 Call Letter continued to support this change, which will be applied for the 2020 Star Ratings.

For beneficiaries who were enrolled in the contract's MTM program for less than 60 days at any time in the measurement year:

- Continue to exclude them from the measure calculation if they did not receive a CMR within this timeframe.
- (New) Include them in the denominator and the numerator if they received a CMR within this timeframe.

For example, a beneficiary was enrolled in the MTM program on November 2 of the measurement year through December 31 (less than 60 days of MTM program enrollment).

- If no CMR received by December 31, exclude from measure calculation.
- If CMR received by December 31, include in the denominator and the numerator.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D). In line with PQA measure updates for the 2018 measurement year, in the draft 2020 Call Letter, we proposed to exclude beneficiaries who elected to receive hospice care at any time in the

measurement period and apply this change to the 2020 Star Ratings (instead of applying a Proportion of Days (PDC) adjustment for hospice enrollment as is currently done). This change narrows the population covered by the measure with no other changes. We will implement this non-substantive change for the 2020 Star Ratings and going forward, as supported by comments. See also § 422.184(d)(1). Some commenters suggested additional exclusions or specification changes (such as drugs/classes included); CMS shared this feedback with the measure developer, PQA.

Statin Use in Persons with Diabetes (SUPD) (Part D). In the CY 2019 Call Letter, the SUPD measure was added to the 2019 Star Ratings with a weight of 1 as a first year measure, then to have an increased weight of 3 as an intermediate outcome measure, starting with the 2020 Star Ratings (based on 2018 data). In response to the draft CY 2020 Call Letter, a majority of commenters opposed this measure's category, and some stated that it is misaligned compared to the Part C Statin Therapy for Patients with Cardiovascular Disease measure (which is a process measure). Other arguments included that the SUPD measure specifications require two diabetes medication fills to qualify for the denominator, while only a single fill of a statin drug is required to be counted in the numerator. Commenters said this does not indicate a level of medication compliance needed to categorize it as an intermediate outcome measure. For the 2020 Star Ratings, we will keep this measure's weight at 1 as a new measure while we further review this measure's category and consider if CMS should propose to change the technical specifications to reclassify it in the future. Commenters also suggested that statin intolerant patients be excluded from the measure denominator or that the measure should include non-statin therapies; CMS shared this feedback with the measure developer, PQA.

Improvement measures (Part C & D). After consideration of the comments about the improvement measures, we are finalizing our proposal. We appreciate the comments related to changing the weight of the Improvement measures and changing the methodology for operationalizing the hold harmless policy for the overall Rating. We will take these comments into consideration as we make future enhancements. The measures used to calculate the 2020 improvement measures are listed in Table 1.

Table 1: 2020 Star Ratings Improvement Measures

Part C or D	Measure	Measure Type	Weight*	Improvement Measure
C	Breast Cancer Screening	Process Measure	1	Yes
C	Colorectal Cancer Screening	Process Measure	1	Yes
C	Annual Flu Vaccine	Process Measure	1	Yes
C	Improving or Maintaining Physical Health	Outcome Measure	3	No
C	Improving or Maintaining Mental Health	Outcome Measure	3	No
C	Monitoring Physical Activity	Process Measure	1	Yes
C	Adult BMI Assessment	Process Measure	1	Yes
C	Special Needs Plan (SNP) Care Management	Process Measure	1	Yes

Part C or D	Measure	Measure Type	Weight*	Improvement Measure
C	Care for Older Adults – Medication Review	Process Measure	1	Yes
C	Care for Older Adults – Functional Status Assessment	Process Measure	1	Yes
C	Care for Older Adults – Pain Assessment	Process Measure	1	Yes
C	Osteoporosis Management in Women who had a Fracture	Process Measure	1	Yes
C	Diabetes Care – Eye Exam	Process Measure	1	Yes
C	Diabetes Care – Kidney Disease Monitoring	Process Measure	1	Yes
C	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	Yes
C	Rheumatoid Arthritis Management	Process Measure	1	Yes
C	Reducing the Risk of Falling	Process Measure	1	Yes
C	Improving Bladder Control	Process Measure	1	Yes
C	Medication Reconciliation Post-Discharge	Process Measure	1	Yes
C	Plan All-Cause Readmissions	Outcome Measure	3	Yes
C	Getting Needed Care	Patients' Experience and Complaints Measure	1.5	Yes
C	Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	Yes
C	Customer Service	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Care Coordination	Patients' Experience and Complaints Measure	1.5	Yes
C	Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Health Plan Quality Improvement	Improvement Measure	5	No
C	Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5	Yes
C	Reviewing Appeals Decisions	Measures Capturing Access	1.5	Yes
C	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
C	Statin Therapy for Patients with Cardiovascular Disease	Process Measure	1	Yes
D	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
D	Appeals Auto–Forward	Measures Capturing Access	1.5	Yes
D	Appeals Upheld	Measures Capturing Access	1.5	Yes
D	Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Drug Plan Quality Improvement	Improvement Measure	5	No
D	Rating of Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1.5	Yes
D	MPF Price Accuracy	Process Measure	1	No

Part C or D	Measure	Measure Type	Weight*	Improvement Measure
D	Medication Adherence for Diabetes Medications	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	Yes
D	MTM Program Completion Rate for CMR	Process Measure	1	Yes
D	Statin Use in Persons with Diabetes	Intermediate Outcome Measure	1	Yes

*Starting with the 2021 Star Ratings, Patients' Experience and Complaints and Access measures will receive a weight of 2.

Temporary Removal of Measure from the 2020 Star Ratings

Controlling High Blood Pressure (Part C). Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association, the National Committee for Quality Assurance (NCQA) is implementing updates to the Controlling High Blood Pressure measure for HEDIS 2019. NCQA has revised the blood pressure target to <140/90 mmHg. NCQA has also made some structural changes to the measure that include allowing two outpatient encounters to identify the denominator and removing the medical record confirmation for hypertension, allowing the use of telehealth services for one of the outpatient encounters in the denominator, adding an administrative approach that utilizes CPT category II codes for the numerator, and allowing remote monitoring device readings for the numerator. Given the change to the blood pressure target and our established methodology for moving measures with substantive changes to the display page (42 CFR 422.164(e)(1)(i)), we will move this measure to the display page for the 2020 and 2021 Star Ratings. The vast majority of commenters to the draft Call Letter supported moving this measure to the display page temporarily. We have proposed to move this back into the 2022 Star Ratings in the CY 2020 Proposed Rule (83 FR 55021). When a measure is temporarily moved to the display page, we continue to expect MA contracts to focus on improvements in areas such as controlling high blood pressure that are critical to the overall health and well-being of Medicare beneficiaries.

2020 Star Ratings Program and the Categorical Adjustment Index

The Categorical Adjustment Index (CAI) was first implemented in the 2017 Star Ratings program to address the within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and dual eligible (LIS/DE) and disability. The values and abridged details of the methodology are provided in the annual Medicare Part C & D Star Ratings Technical Notes available on the CMS webpage at https://go.cms.gov/partcanddstarratings. Additional details of the CAI methodology can be found in the CAI Methodology Supplement available at the same link.

There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best address the impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries covered under the contracts. Commenters to the draft Call Letter

encouraged CMS to continue to collaborate with ASPE, measure stewards, and stakeholders and work toward a permanent solution to addressing the impact of social risk factors on ratings. CMS is continuing to review the efforts in this space and to work with ASPE, measure stewards, and stakeholders regarding measure-specific adjustments. Commenters also questioned whether CMS was continuing adjustments for contracts that exclusively serve the population of beneficiaries in Puerto Rico. As stated in the draft Call Letter, all 2019 Star Ratings methodologies remain the same unless otherwise noted in the Call Letter. CMS continues to recognize the additional challenge unique to Puerto Rico with the medication adherence measures in the Star Ratings program due to the lack of LIS. Thus, CMS will continue to reduce the weights for the adherence measures to zero for the summary and overall rating calculations and will maintain the weight of three for the adherence measures for improvement measure calculations.

The final report of the findings of the two-year trial period by National Quality Forum (NQF) that temporarily lifted the restriction and allowed risk-adjustment of performance measures for socioeconomic status (SES) and other demographic factors was released in July 2017.[10] NQF has launched a three-year initiative to further examine and consider social risk adjustment to allow evidence as to whether a change in their longstanding policy prohibiting adjustment for SES and other demographic factors (known as "risk adjustment" in this context) should be revised.

We have contracted with NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether any modifications to the specification would be appropriate.

The PQA examined their medication adherence measures, which are currently used in the Star Ratings program, for potential risk adjustment (i.e., adjustment for SES and demographic factors).[11] Beginning in 2018, the PQA included in the 2018 PQA Measure Manual draft recommendations on risk adjustment of the three medication adherence measures: Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol. The draft recommendations are as follows:

- All three adherence measures should be risk adjusted for sociodemographic status (SDS) characteristics to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/LIS status, and disability status.

[10] NQF's Final Report can be accessed using the following link: http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx

[11] The PQA summary can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars

- The three adherence measures should be stratified by the beneficiary-level SDS characteristics listed above to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA indicated that the risk-adjusted adherence measures will be submitted through the NQF consensus development process for maintenance of the measures (NQF Endorsed #0541). If endorsed by NQF, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures (for 2021 measurement year or beyond).

In the meantime, CMS plans to test the inclusion of stratifications by age, gender, dual eligibility/LIS status, and disability status in the Medication Adherence Patient Safety Reports to Part D sponsors beginning with the 2019 measurement year.

NCQA's 2019 HEDIS Volume 2 includes the revised specifications of four measures used in the MA Star Ratings. The revised specifications for Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions[12] are applicable to MA contracts to meet the MA program's reporting requirements. CMS is considering how to best incorporate the information provided by the stratified reporting in future years of the Star Ratings.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), as required in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185), released the first in a two-part series of Reports to Congress (RTC) in December 2016.[13] ASPE's second report is due in the fall of 2019. CMS will review this report when it is released. In the meantime, CMS continues to be in dialogue with ASPE about potential options for future MA Star Ratings.

Based on commenters' support of the draft Call Letter, and stakeholders' feedback on previous Call Letters and the CY 2019 Final Rule (CMS-4182-F) published in April 2018 (83 FR 16440), CMS is expanding the adjusted measure set for the determination of the 2020 CAI values. The methodology for the 2020 Star Ratings is the same methodology that has been finalized for the 2021 Star Ratings in the CY 2019 Final Rule. See 42 CFR §§ 422.166(f)(2) and 423.186(f)(2). Some commenters opposed expanding the adjusted measure set, because this results in larger downward adjustments for contracts with low percentages of LIS/DE enrollees. While the downward adjustment for plans with low percentages of LIS/DE enrollees will be greater under this methodology, the research we conducted prior to

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[12] A summary of the NCQA analysis and recommendations can be accessed using the link that follows: http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act

[13] ASPE's first Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs can be accessed using the link that follows: https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance- under-medicares-value-based-purchasing-programs.

implementing the CAI provided evidence that within-contract differences exist in performance for LIS/DE beneficiaries and non-LIS/DE beneficiaries on a subset of Star Ratings measures. Therefore, this expansion is intended to level the playing field between contracts to better reflect differences in performance, rather than differences in the populations being served across contracts. Based on this goal, CMS is moving forward with expanding the adjusted measure set as proposed. For the 2020 CAI adjusted measure set, all measures identified as candidate measures will be included in the determination of the 2020 CAI values. A measure will be included as a candidate measure if it remains after applying the following four bases for exclusions:

- The measure is already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures);
- The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures);
- The measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or
- The measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures).

The candidate measure set for the 2020 CAI is as follows: Adult BMI Assessment, Annual Flu Vaccine, Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Diabetes Care – Eye Exam, Diabetes Care – Kidney Disease Monitoring, Improving Bladder Control, Medication Reconciliation Post-Discharge, MTM Program Completion Rate for CMR, Monitoring Physical Activity, Osteoporosis Management in Women who had a Fracture, Plan All-Cause Readmissions, Reducing the Risk of Falling, Rheumatoid Arthritis Management, Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, Medication Adherence for Cholesterol, Statin Therapy for Patients with Cardiovascular Disease, and Statin Use in Persons with Diabetes.

Previously, the decision criteria used to select measures from the candidate measure set for adjustment were (1) a median absolute difference between LIS/DE and non-LIS/DE beneficiaries of 5 percentage points or more and/or (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. This selection rule was originally developed based on a goal of adjusting measures only when there are substantive LIS/DE within-contract measure disparities. The expansion of the adjusted measure set eliminates these additional criteria about the size of the within-contract differences, which relied on the analysis of the variability of the within-contract differences of LIS/DE and non-LIS/DE beneficiaries. In keeping with our commitment to transparency, a summary of the analysis of the candidate measure set that

includes the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences is posted at http://go.cms.gov/partcanddstarratings.

2020 Categorical Adjustment Index (CAI) Values

MA contracts have up to three mutually exclusive and independent CAI adjustments – one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). PDPs have one adjustment for the Part D summary rating. Tables 2-13 provide the rating-specific categories for classification of contracts based on the percentage of LIS/DE and disabled beneficiaries along with the final adjustment categories. We also note the we are continuing from prior years the additional adjustment by calculating a modified value for the percentage of LIS/DE for contracts that operate solely in Puerto Rico (i.e., contracts with service areas entirely in Puerto Rico), because Puerto Rican beneficiaries are not eligible for LIS.

Table 2 provides the range for the percentages that correspond to the LIS/DE categories determined by dividing the distribution of MA contracts' LIS/DE percentages into ten equal-sized groups. Table 3 provides the range of the percentages that correspond to the disability quintiles for the categorization of MA contracts for the CAI for the overall Star Rating.

The upper limit for each category is not included in that category, but rather the next higher category. For example, if a contract's percentage of LIS/DE beneficiaries is 50.5%, the contract's LIS/DE initial category is L8. The exceptions for the upper limit exclusion for an initial group are the tenth initial category for LIS/DE and the fifth quintile for disability.

Table 2: Categorization of MA Contracts into Initial LIS/DE Groups for the Overall Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 5.676443
L2	5.676443 to less than 8.948963
L3	8.948963 to less than 11.175889
L4	11.175889 to less than 14.780296
L5	14.780296 to less than 19.828475
L6	19.828475 to less than 28.116922
L7	28.116922 to less than 44.240275
L8	44.240275 to less than 74.807539
L9	74.807539 to less than 100.00000
L10	100.000000

Table 3: Categorization of MA Contracts into Disability Quintiles for the Overall Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 14.517881
D2	14.517881 to less than 20.616671
D3	20.616671 to less than 27.537428
D4	27.537428 to less than 39.480724
D5	39.480724 to 100.000000

Table 4 provides the description of each of the final adjustment categories for the overall Star Rating for MA contracts and the associated values of the CAI for each final adjustment category.

Table 4: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L3	D1-D2	-0.042454
2	L4-L8	D1	-0.018356
	L4-L6	D2	
3	L1-L6	D3	-0.003555
4	L9-L10	D1-D2	0.039921
	L7-L8	D2-D3	
	L1-L8	D4	
	L1-L7	D5	
5	L9-L10	D3-D4	0.133626
	L8-L9	D5	
6	L10	D5	0.167650

Tables 5 and 6 provide the range of the percentages that correspond to the initial LIS/DE groups and disability quintiles for the initial categories for the determination of the CAI values for the Part C summary rating.

Table 5: Categorization of MA Contracts into Initial LIS/DE Groups for the Part C Summary Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 5.558118
L2	5.558118 to less than 8.585859
L3	8.585859 to less than 11.062133
L4	11.062133 to less than 14.516227

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L5	14.516227 to less than 19.228066
L6	19.228066 to less than 27.355519
L7	27.355519 to less than 42.670760
L8	42.670760 to less than 74.043808
L9	74.043808 to less than 100.00000
L10	100.000000

Table 6: Categorization of MA Contracts into Disability Quintiles for the Part C Summary Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 14.322701
D2	14.322701 to less than 20.016933
D3	20.016933 to less than 27.192499
D4	27.192499 to less than 39.132112
D5	39.132112 to 100.000000

Table 7 provides the description of each of the final adjustment categories for the Part C summary rating and the associated value of the CAI for each final adjustment category.

Table 7: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L9	D1	0.001152
	L1-L6	D2	
2	L7	D2	0.014974
	L1-L7	D3-D5	
3	L10	D1	0.080025
	L8-L10	D2-D4	
4	L8-L10	D5	0.095022

Tables 8 and 9 provide the range of the percentages that correspond to the initial LIS/DE groups and the disability quintiles for the initial categories for the determination of the CAI values for the Part D summary rating for MA-PDs.

Table 8: Categorization of MA-PD Contracts into Initial LIS/DE Groups for the Part D Summary Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 5.789192
L2	5.789192 to less than 9.367454
L3	9.367454 to less than 11.360697
L4	11.360697 to less than 15.014489
L5	15.014489 to less than 21.634509
L6	21.634509 to less than 31.215753
L7	31.215753 to less than 53.136112
L8	53.136112 to less than 82.253813
L9	82.253813 to less than 100.00000
L10	100.000000

Table 9: Categorization of MA-PD Contracts into Disability Quintiles for the Part D Summary Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 14.909782
D2	14.909782 to less than 21.575847
D3	21.575847 to less than 28.825467
D4	28.825467 to less than 41.935484
D5	41.935484 to 100.000000

Table 10 provides the description of each of the final adjustment categories for the Part D summary rating for MA-PDs and the associated values of the CAI for each final adjustment category.

Table 10: Final Adjustment Categories and CAI Values for the Part D Summary Rating for MA-PDs

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L7	D1	-0.082197
2	L1-L5	D2	-0.045536

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
3	L1-L5	D3	-0.004424
	L1-L4	D4	
4	L8	D1	0.028339
	L6-L8	D2-D3	
	L5-L6	D4	
	L1-L6	D5	
5	L9-L10	D1-D3	0.093944
	L7-L9	D4	
	L7	D5	
6	L8-L9	D5	0.210469
7	L10	D4-D5	0.255181

Tables 11 and 12 provide the range of the percentages that correspond to the LIS/DE and disability quartiles for the initial categories for the determination of the CAI values for the Part D summary rating for PDPs. Quartiles are used for both dimensions (LIS/DE and disability) due to the limited number of PDPs as compared to MA contracts.

Table 11: Categorization of PDP Contracts into LIS/DE Quartiles for the Part D Summary Rating

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 1.812445
L2	1.812445 to less than 4.384002
L3	4.384002 to less than 27.635066
L4	27.635066 to 100.000000

Table 12: Categorization of PDP Contracts into Disability Quartiles for the Part D Summary Rating

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
D1	0.000000 to less than 7.499709
D2	7.499709 to less than 12.338617
D3	12.338617 to less than 21.856925
D4	21.856925 to 100.000000

Table 13 provides the description of each of the final adjustment categories for the Part D summary rating for PDPs and the associated value of the CAI per final adjustment category.

Please note that the CAI values for the Part D summary rating for PDPs are different from the CAI values for the Part D summary rating for MA contracts. Categories are chosen to enforce monotonicity and to yield a minimum of 10 contracts per final adjustment category. There are four final adjustment categories for PDPs for the Part D summary rating.

Table 13: Final Adjustment Categories and CAI Values for the Part D Summary Rating for PDPs

Final Adjustment Category	LIS/DE Quartile	Disability Quartile	CAI Value
1	L1	D1-D2	-0.495192
2	L2	D1-D2	-0.320486
3	L1-L2 L3	D3-D4 D1-D4	-0.209888
4	L4	D1-D4	0.189815

Extreme and Uncontrollable Circumstances Policy

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide beneficiaries with important medical care and prescription drug coverage. These extreme and uncontrollable circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program. We proposed to adjust the 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period using a similar methodology to the one adopted for the 2019 Star Ratings in the CY 2019 Call Letter. To promote transparency regarding the disaster adjustments, we committed in the draft Call Letter to providing in future data releases additional information on which contracts were eligible for disaster adjustments. For the 2019 Star Ratings, which were adjusted for the disasters that occurred during the 2017 performance period (Hurricanes Harvey, Irma, and Maria, and the wildfires in California), 77 contracts met the 25 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas at the time of the disaster. Affected contracts reverted to the prior year's rating an average of five times for Part C measures and three times for Part D measures. For the 2019 Star Ratings, 57 contracts met the 60 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas and had their numeric values excluded from the clustering algorithm so they did not influence cut points. There were fewer disasters that trigger the extreme and uncontrollable circumstance policy in 2018 than in 2017, and fewer contracts were impacted, so we anticipate even fewer extreme and uncontrollable circumstance adjustments to the 2020 Star Ratings than were made to the 2019 Star Ratings.

In the CY 2020 Proposed Rule, published in the Federal Register on November 1, 2018 (83 FR

55021), we proposed in paragraph (i) of §§ 422.166 and 423.186 a set of rules for adjusting the calculation of Star Ratings for the Parts C and D organizations that are impacted by extreme and uncontrollable circumstances that occurred during the performance period for the 2022 Star Ratings year and beyond. The Advance Notice/Call Letter process will be used for the 2020 Star Ratings.

Most comments submitted to the draft Call Letter included support for CMS using an adjustment for disasters in the 2020 Star Ratings similar to the one used in the 2019 Star Ratings. A few commenters raised issues related to the adjustment we proposed for contracts affected by disasters in consecutive years. For example, some suggested that we look back to the most recent unaffected year's data or look back 3 years, while others acknowledged our concern with using data from several years prior. We are finalizing our proposed policy because we are concerned about older data continuing to be pulled forward in the Star Ratings and about including too many measurement periods in one year of Star Ratings. We also must consider both the administrative complexity and operational feasibility of using different thresholds for contracts affected by disasters in different ways, as well as the need for our methodology to be transparent and understandable to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings. Note we expect few doubly-affected contracts in the 2020 Star Ratings. Further, as we finalized beginning January 1, 2016, the regulations at §§ 422.504(o) and 423.505(p) require MA organizations and Part D sponsors to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. We expect that these business continuity plans will address many of the issues that would result in an impact on the performance of an affected contract where there are extreme and uncontrollable circumstances that occur in successive years or over more than one performance period.

Several commenters wanted CMS to continue the adjustments to the ratings for contracts operating in Puerto Rico that were initiated because of the 2017 disasters given the ongoing hurricane recovery during the 2018 performance period. CMS will not adjust the 2020 Star Ratings for Puerto Rico plans based on the hurricanes in 2017, except for HOS measures as finalized in the 2019 Call Letter (the 2020 Star Ratings use HOS data collected in 2018 and reflect experiences over the past 12 months). We believe it is appropriate to limit adjustments for a single extreme and uncontrollable circumstance to one year to avoid adversely impacting operational timelines, to limit impacts on contracts not impacted by disasters, and to preserve transparency of the Star Ratings for consumers by not using data from many different measurement years. We note that for the 2019 Star Ratings, affected contracts did not revert to the prior year's measure rating much on average, and in Puerto Rico contracts reverted even less often than did other affected contracts. We clarify below that all contracts can work with NCQA to request modifications to the samples for measures that require medical record review. We

also remind commenters that Puerto Rico contracts have adherence measures weighted zero in the overall Star Ratings calculations.

A few commenters requested that CMS exclude beneficiaries in impacted areas from ratings. For many measures, this is not operationally feasible. For example, this would require modifications to CAHPS and HOS sampling, as well as to HEDIS reporting requirements. Other measures do not have beneficiary-level data that could be adjusted. A few commenters also expressed concern about impacts of the disaster policy on non-disaster contracts. As described above, the impact on the 2019 Star Ratings as a result of the adjustments permitted under this aspect of the overall methodology was minimal, and the projected impact on the 2020 Star Ratings based on extreme and uncontrollable events that occurred during the 2018 performance period is even smaller.

Below we describe how we will identify which contracts were impacted by extreme and uncontrollable circumstances as well as how to adjust the Star Ratings measures for CY2020 Star Ratings. This policy mirrors in large part the policy proposed in CMS-4185-P and is largely the same as that described in the final 2019 Call Letter and used for 2019 Star Ratings, with two substantive exceptions. First, we will eliminate the difference-in-differences adjustment for survey data. The difference-in-differences adjustment showed no consistent, negative impact of extreme and uncontrollable circumstances on the 2019 Star Ratings; therefore, we will eliminate this adjustment to simplify the methodology. Second, we will clarify the rules around measures with missing or biased data in the prior or current year.

Identification of Affected Contracts

We will first identify MA and Part D contracts for which extreme and uncontrollable circumstances may impact their performance on Star Ratings measures and/or may impact their ability to collect the necessary measure-level data. These “affected contracts” will be the contracts eligible for the adjustments that take into account the effects of the extreme and uncontrollable circumstances.

Affected contracts are contracts that meet all of the following criteria during the performance period for the Star Ratings:

(1) The service area is within an “emergency area” during an “emergency period” as defined in Section 1135(g) of the Act.

(2) The service area is within a county or county-equivalent entity designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under Section 1135 of the Act based on the same triggering event(s).

(3) A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and reward factor calculations) of the enrollees under the

contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

The policy is tailored to the specific areas experiencing the extreme and uncontrollable circumstance. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers located in and serving specific physical locations. For purposes of this policy, a narrower geographic scope than the full emergency area ensures that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects. We identify an area as having experienced extreme and uncontrollable circumstances if it is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act, and also is within a county or county-equivalent entity designated in a major disaster declaration under the Stafford Act that served as a condition precedent for the Secretary's exercise of the 1135 waiver authority (https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx). Major disaster areas are identified and can be located on the Federal Emergency Management Agency (FEMA) Web site at https://www.fema.gov/disasters. We use the incident period start date to determine which year of Star Ratings could be affected, regardless of whether the incident period end date crosses the calendar year.

Table 14 lists all of the Section 1135 waivers that could affect the 2020 Star Ratings.

Table 14: List of Section 1135 Waivers Issued in Relation to the FEMA Major Disaster Declarations

Section 1135 Waiver Date Issued	Waiver or Modification of Requirements Under Section 1135 of the Social Security Act	FEMA Major Disaster Declaration	FEMA Incident Type	Affected State	Incident Start Date	Declared Major Disaster
12/03/2018	AK as the result of earthquake	DR-4413*	Earthquake	AK	11/30/2018	01/31/2019
11/13/2018	CA as the result of wildfires	DR-4407	Wildfire	CA	11/08/2018	11/12/2018
10/25/2018	MP as the result of typhoon Yutu	DR-4404	Typhoon	MP	10/24/2018	10/26/2018
10/11/2018	GA as the result of hurricane Michael	DR-4400	Hurricane	GA	10/09/2018	10/14/2018
10/09/2018	FL as the result of hurricane Michael	DR-4399	Hurricane	FL	10/07/2018	10/11/2018
09/12/2018	VA as the result of hurricane Florence	DR-4401	Hurricane	VA	09/08/2018	10/15/2018
09/11/2018	SC as the result of hurricane Florence	DR-4394	Hurricane	SC	09/08/2018	09/16/2018
09/11/2018	NC as the result of hurricane Florence	DR-4393	Hurricane	NC	09/07/2018	09/14/2018

*Declared a major disaster subsequent to the release of the draft 2020 Call Letter.

Table 15 lists the Individual Assistance counties from all of the FEMA major disaster declarations.

Table 15: Individual Assistance Counties in FEMA Major Disaster Declared States

FEMA Declaration	State	FEMA Individual Assistance Counties
DR-4393	North Carolina	Anson, Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Hyde, Johnston, Jones, Lee, Lenoir, Moore, New Hanover, Onslow, Orange, Pamlico, Pender, Pitt, Richmond, Robeson, Sampson, Scotland, Union, Wayne, Wilson
DR-4394	South Carolina	Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Marion, Marlboro
DR-4399	Florida	Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Leon, Liberty, Taylor, Wakulla, Washington
DR-4400	Georgia	Baker, Crisp, Decatur, Dougherty, Early, Grady, Lee, Miller, Mitchell, Seminole, Terrell, Thomas, Worth
DR-4401	Virginia	None
DR-4404	Northern Mariana Islands	Northern Islands, Rota, Saipan, Tinian
DR-4407	California	Butte, Los Angeles, Ventura
DR-4413*	Alaska	Anchorage (Borough), Kenai Peninsula (Borough), Matanuska-Susitna (Borough)

*Declared a major disaster subsequent to the release of the draft 2020 Call Letter.

To further narrow the scope of this policy to ensure it is applied to those contracts most likely to have experienced the greatest adverse effects, we will limit this policy to Individual Assistance disaster declarations. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program (https://www.fema.gov/disaster-declaration-process). We focus on counties eligible for Individual Assistance as a result of a major disaster because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Therefore, adjustments to the Star Ratings are most appropriately targeted to areas where beneficiaries were eligible for individual and household assistance as a result of the extreme and uncontrollable circumstance.

To determine whether a contract was impacted (such that it would be an "affected contract" eligible for adjustments), we will compare the number of enrollees in the Individual Assistance area at the time of the extreme and uncontrollable circumstance compared to the number of enrollees outside the Individual Assistance area. Using the Individual Assistance major disaster declaration as a requirement for the extreme and uncontrollable circumstance policy ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings, and targeting the specific area affected by the extreme and uncontrollable circumstance.

The Hurricanes Florence and Michael, Typhoon Yutu, the California wildfires, and the Alaska earthquake trigger the extreme and uncontrollable circumstance policy as, during the performance period for the 2020 Star Ratings, there were areas identified as "emergency areas" for "emergency periods" under Section 1135(g) as a result of these natural disasters; there were Stafford Act declarations of a major disaster applicable to them; the Secretary did exercise authority under Section 1135 of the Act as a result of these disasters; and there are enrollees

residing in FEMA-designated Individual Assistance areas at the relevant time. During the measurement year for the 2020 Star Ratings, the effects of Hurricanes Florence and Michael, Typhoon Yutu, the California wildfires, and the Alaska earthquake were significant for Medicare beneficiaries, as well as for the Parts C and D organizations that provide medical care and prescription drug coverage for them. We will limit adjustments to the Star Ratings to affected contracts for these major disasters. MA plans complete many preventive screenings at the end of the calendar year so disasters in this period may have an inordinate impact on 2020 Star Ratings. Finally, beneficiaries responding to CMS surveys early in 2019 will be reflecting predominately on events in late 2018 so these disasters may impact survey results used for the 2020 Star Ratings.

Contracts that do not meet the definition of an "affected contract" or the parameters discussed below will not be eligible for any adjustments to the 2020 Star Ratings under this policy.

CAHPS Adjustments:

For CAHPS, CMS will take into account the effects of these extreme and uncontrollable circumstances in the following two ways for affected contracts:

First, for all contracts (including affected contracts), the MA organization will be required to administer the 2019 CAHPS survey unless the contract requests and we approve an exception because a substantial number of their enrollees have been displaced due to a FEMA-designated disaster in 2018 and it would be practically impossible to contact the required sample for the survey. We will make the exception available only to affected contracts that can demonstrate meeting this standard.

Second, our adjustment is for affected contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. These affected contracts will receive the higher of the 2019 or 2020 Star Rating (and corresponding measure score for the Star Ratings year selected) for each CAHPS measure (including the annual flu vaccine measure). The 25% threshold avoids including contracts with very few enrollees impacted. We use the measure-level Star Rating rather than measure-level scores for the comparison because the measure stars are used to calculate the overall Star Rating and the measure-level cut points can change each year. The measure-level scores for contracts with very few enrollees impacted should not be adversely affected by these extreme and uncontrollable circumstances.

In some cases contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas that were affected by disasters that began in 2018 were also affected by disasters in 2017. These doubly-affected contracts will receive the higher of the 2020 Star Rating or what the 2019 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we

will use the corresponding measure score for the Star Ratings year selected). For example, if a doubly-affected contract reverted back to the 2018 Star Rating on a given measure in the 2019 Star Ratings, the 2018 Star Rating will *not* be used in determining the 2020 Star Rating. Rather the 2020 Star Rating will be compared to what the 2019 Star Rating would have been absent any disaster adjustments.

For all adjustments, if the Star Rating is the same in both years we will use the Star Rating and measure score from the most recent year.

HOS Adjustments:

For the HOS survey, we will follow similar procedures as CAHPS but the adjustment for 2017 disasters (listed in Tables 15 and 16 of the final CY 2019 Call Letter) will be to the 2020 Star Ratings, and the adjustment for 2018 disasters (listed in Tables 14 and 15 of this CY 2020 Call Letter) will be to the 2021 Star Ratings. This is due to the longitudinal nature of the HOS data collection. The HOS measures for the 2020 Star Ratings are based on HOS data collected from April through July 2018. The HOS methodology for the 2020 Star Ratings was finalized in the final 2019 Call Letter as it reflects data from an earlier timeframe. As we stated above, the difference-in-differences adjustment is not being used since it showed no consistent, negative impact of extreme and uncontrollable circumstances. The HOS data collected in 2019 are used for the 2021 Star Ratings and reflect health statuses over the past 12 months, so responses may reflect health statuses during 2018 disasters. For the HOS survey, we will follow procedures similar to CAHPS and have two adjustments for affected contracts:

First, the MA organization holding an affected contract will be required to administer the 2019 HOS surveys unless the contract requests and CMS approves an exception because a substantial number of the contract enrollees have been displaced due to a FEMA-designated disaster in 2018 and it would be practically impossible to contact the required sample for the survey. The exception will be available only for affected contracts that can demonstrate meeting this standard.

Second, affected contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance will receive the higher of the 2021 or 2020 Star Rating (and corresponding measure score for the Star Ratings year selected) for each HOS outcome measure and HEDIS-HOS measure in the 2021 Star Ratings. The 25% threshold avoids including contracts with very few enrollees impacted. Please see discussion above for more details.

For all adjustments, if the Star Rating is the same in both years we will use the Star Rating and measure score from the most recent year. Our policy for cut points for non-CAHPS measures used in the 2020 Star Ratings is addressed below.

HEDIS Adjustments:

For HEDIS, all affected contracts will be required to report HEDIS data to CMS unless the MA organization of an affected contract requests and receives from CMS an exception because the MA organization cannot obtain both administrative and medical record data necessary for HEDIS. Separate and apart from our Star Ratings methodology and adjustments, all contracts, including those impacted by disasters in previous years, can work with NCQA to request modifications to the samples for measures that require medical record review. For affected contracts with at least 25% of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we will take the higher of the 2019 or 2020 Star Rating (and corresponding measure score for the Star Ratings year selected) for each HEDIS measure. Please see the discussion explaining our rationale for the 25% cutoff.

In some cases contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas that were affected by disasters that began in 2018 were also affected by disasters in 2017. These doubly-affected contracts will receive the higher of the 2020 Star Rating or what the 2019 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we will use the corresponding measure score for the Star Ratings year selected).

For all adjustments, if the Star Rating is the same in both years we will use the Star Rating and measure score from the most recent year.

Other Star Ratings Measure Adjustments:

Subject to the exclusion below, for all other measures for affected contracts with at least 25% of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we will take the higher of the 2019 or 2020 measure Star Rating (and corresponding measure score for the Star Ratings year selected).

In some cases contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas that were affected by disasters that began in 2018 were also affected by disasters in 2017. These doubly-affected contracts will receive the higher of the 2020 Star Rating or what the 2019 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we will use the corresponding measure score for the Star Ratings year selected).

For all adjustments, if the Star Rating is the same in both years we will use the Star Rating and measure score from the most recent year.

We will exclude from this adjustment policy the following measures: Part C Call Center – Foreign Language Interpreter and TTY Availability and Part D Call Center – Foreign Language Interpreter and TTY Availability because these measures and the underlying performance are

completely in the plan's control; we believe therefore that there should be no impact from the declaration of a disaster on plan performance in these areas.

Improvement Measure(s) and Missing Data Rules:

Currently, contracts must have data for at least half of the attainment measures used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For affected contracts that revert back to the data underlying the 2019 Star Rating for a particular measure under our policy to address the effects of an extreme and uncontrollable circumstance, that measure will be excluded from the applicable improvement measure and excluded from the measure count for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure for the 2020 (and, for HOS and HEDIS-HOS, 2021) Star Ratings. That is, we will follow our usual rule where to receive a Star Rating in the improvement measures a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures. Contracts affected by disasters will not have the option of reverting to the prior year's improvement rating.

Except in cases where an exception was granted as described earlier, for all measures eligible for an extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate, it is too new, or it is too small), the final measure rating will come from the current year (that is, it will be treated as missing). This measure will be excluded from the contract's improvement score(s) following our usual rules.

Cut Points for Non-CAHPS Measures:

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to all the measures' numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. We will exclude from this clustering algorithm the numeric values for affected contracts with 60% or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. We are proposing that these contracts be excluded to ensure that any impact of the extreme and uncontrollable circumstance on their measure-level scores will not have an impact on the cut points or measure ratings for other contracts. However, these cut points calculated for all other contracts will be used to assess these contracts' 2020 measure Star Ratings (which will be compared to the contracts' 2019 measure Star Ratings to determine which is higher, and therefore used for the affected contracts' 2020 Star Ratings calculations, per above).

Similarly, affected contracts with 60% or more of their enrollees impacted will also be excluded from the determination of the performance summary and variance thresholds for the Reward

Factor. However, these contracts will still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

2020 Star Ratings Measures

Members Choosing to Leave the Plan (Part C & D). CMS will use additional data to identify beneficiaries leaving a contract due to a move out of the contract service area since a move out of the service area is considered an involuntary disenrollment. Currently, if a member has a disenrollment reason code (DRC) 92, the member is not included in the numerator for this measure since this code captures moves out of the contract service area. In some cases, moves out of the service area are being recorded in the CMS systems using codes other than DRC 92 and would, consequently, be included in the numerator. We will exclude moves out of service area that used codes other than DRC 92. These are involuntary disenrollments even if they are not coded DRC 92 and should not be counted against the measure. Commenters to the draft Call Letter expressed support for the use of additional data, but a few commenters asked for more detail on this data source. We will exclude from the numerator disenrollees for whom the new contract service area does not overlap with the old contract service area; we will identify these enrollees by comparing the service area from the measurement year of the contract the beneficiary is leaving to the service area from the measurement year and the following year of the contract into which the beneficiary is enrolling. We use the service area from the measurement year and the following year of the contract the beneficiary enrolled into, because in many cases disenrollments occur during open enrollment such that the beneficiary will enroll into the new plan in the following year.

2020 Display Measures

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that are transitioned from inclusion in the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed solely for informational purposes. Organizations and sponsors will have the opportunity to preview the data for their display measures prior to release on CMS's website. Data for measures moved to the display page continue to be collected and monitored; poor scores on display measures may reveal underlying compliance and performance issues that are subject to enforcement actions by CMS. All 2019 display measures will continue to be shown as display measures on CMS.gov in 2020 unless noted below.

CMS will continue to solicit feedback on new and updated measures through the Call Letter process, as well as continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Going forward as codified at § 422.164(c)(2-4), § 423.184(c)(2-4), § 422.164(d)(2), and § 423.184(d)(2), new measures and measures with substantive specification changes will be on the display page for at least two years prior to becoming a Star Ratings measure.

New 2020 Display Measures

Transitions of Care (Part C). CMS is working with NCQA to expand efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to home. The intent of the measure is to improve the quality of care transitions from an inpatient setting to home, as effective transitioning will help reduce hospital readmissions, costs, and adverse events.

The Transitions of Care measure excludes members in hospice and is based on the number of discharges, not members. The measure includes the percent of discharges for members 18 years or older who have each of the four indicators during the measurement year:

1. Notification of Inpatient Admission: Documentation of primary care practitioner notification of inpatient admission on the day of admission or the following day.
2. Receipt of Discharge Information: Documentation of primary care practitioner receipt of specific discharge information on the day of discharge or the following day.
3. Patient Engagement After Inpatient Discharge: Documentation of patient engagement (for example, office visits, visits to the home, or telehealth) provided by primary care practitioner within 30 days after discharge.
4. Medication Reconciliation Post-Discharge (which is currently a HEDIS measure): Documentation of medication reconciliation within 30 days of discharge.

Based on analyses of the first year data submitted in June 2018, NCQA is removing the requirement of documenting medication allergies under the *Receipt of Discharge Information* indicator for the HEDIS 2019 specification. We are proceeding to add this measure to the 2020 display page with the intent to propose this measure for future inclusion in the Star Ratings. Most commenters supported the concept of measuring transitions of care, while some offered feedback on how to improve the measure. CMS has shared all comments received on this measure with NCQA, the measure steward.

Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C). CMS is adding to the 2020 display page a new HEDIS measure assessing follow-up care provided after an emergency department visit for patients with multiple chronic conditions. Patients with multiple chronic conditions are more likely to have complex care needs and follow-up after an acute event, like an emergency department visit, can help prevent the development of more severe complications. This measure includes the percentage of emergency department (ED) visits for members 18 years and older who have high-risk multiple chronic conditions who had a follow-up service within 7 days of the ED visit between January 1 and December 24 of the measurement year. The measure is based on ED visits, not members. The following are eligible chronic condition diagnoses. Members must have two or more from this list:

- COPD and asthma
- Alzheimer's disease and related disorders

- Chronic kidney disease
- Depression
- Heart failure
- Acute myocardial infarction
- Atrial fibrillation
- Stroke and transient ischemic attack

The following meet the criteria to qualify as a follow-up service for purposes of the measure:

- An outpatient visit (with or without telehealth modifier)
- A behavioral health visit
- A telephone visit
- Transitional care management services
- Case management visits
- Complex Care Management

The majority of commenters to the draft Call Letter supported this measure, while some commenters asked for additional information about the services that qualify as follow-up. The list above includes the type of visits that qualify for follow-up care. Please note that the value sets or the complete set of codes used to identify the services or conditions included in the measure are routinely updated by NCQA as new codes are added or revised. CMS has shared all comments received on this measure with NCQA, the measure steward.

MPF Price Accuracy (Part D). As stated in the 2019 Call Letter, we proposed enhancements to the MPF Price Accuracy measure to be first published as a display measure in 2020, and then to be considered to be applied to the Star Rating measure for 2022, pending rulemaking. Pending such a change, the current MPF measure will continue in the Star Ratings using the same methodology used for the 2019 Star Ratings. (See Attachment M of the 2019 Technical Notes available on the CMS webpage: http://go.cms.gov/partcanddstarratings.)

These enhancements will better measure the reliability of a contract's MPF advertised prices.

We will implement the following changes for the 2020 and 2021 display of this measure (please see Appendix 1 for a more detailed methodology of these changes):

1. Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the below indexes:
   - The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as:
     (Total amount that PDE is higher than MPF + Total PDE cost) / (Total PDE cost).

- The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as: (Total number of claims where PDE is higher than MPF) / (Total number of claims)
- The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.
- A contract's measure score is computed as:
    - Price Accuracy Score = 100 – ((Price Accuracy Index - 1) x 100)
    - Claim Percentage Score = (1 – Claim Percentage Index) x 100
    - Measure Score = (0.5 x Price Accuracy Score) + (0.5 x Claim Percentage Score)

2. Increase the claims included in the measure:
    - Expand the days' supply of claims included from 30 days to include claims with fills of 28-34, 60-62, or 90-100 days.
    - Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.

3. Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. The PDE cost must exceed the PF cost by at least one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places, using traditional rounding rules.

In this measure, a contract's score is not impacted if PDEs are priced lower than MPF displayed pricing. Only price increases are counted in the numerator for this measure.

The enhancements are largely those that had been previously finalized in the 2018 and 2019 Call Letters. Most of the commenters who were concerned about these enhancements also requested more information to review how the individual scores of specific contracts would change and to compare these scores across sponsors. Prior to releasing the new 2020 display measure, we will continue to provide contract-level preliminary and final MPF Price Accuracy reports to Part D sponsors, which contain claim level information. We will also provide information to contracts about their Accuracy scores using the new specifications.

Retired Display Measure for 2020

Transition Monitoring Program Analysis (TMPA) and Formulary Administration Analysis (FAA) (Part D). Over the past several years, the TMPA and FAA have served as oversight monitoring projects to ensure Part D Sponsors were meeting Medicare Part D formulary

administration and transition requirements. Since the inception of these analyses, CMS has seen an improvement in formulary administration and transition practices. The percentage of contracts exceeding the failure threshold has steadily decreased since the beginning of these analyses. In CY 2012, 27% of contracts included in the TMPA exceeded the failure threshold but in CY 2018, only 3% of contracts included exceeded the failure threshold. Similarly for FAA, in CY 2013, 27% of contracts included in the FAA exceeded the failure threshold but in CY 2017 only 1% of contracts included exceeded the failure threshold. In addition, these analyses are duplicative of other oversight monitoring projects, such as program audits, which has led to an increased burden on plans. As such, CMS has determined that we will not be continuing the TMPA and FAA for CY 2019 and we will discontinue display of these measures. We will continue to perform analyses of formulary administration and transition procedures to ensure sponsors are meeting CMS requirements. However, Part D sponsors will no longer be asked to submit rejected claims files for CMS to perform the TMPA and FAA analyses. CMS will provide information at a later date regarding this work.

Changes to Existing 2020 Display Measures

Use of Opioids at High Dosage and from Multiple Providers (OHDMP) and Antipsychotic Use in Persons with Dementia (APD) (Part D). The OHDMP measure is the percentage of Medicare Part D beneficiaries ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days. The APD measure is the percentage of Medicare Part D beneficiaries 65 years or older with a diagnosis of or prescriptions for the treatment of dementia (i.e., cholinesterase inhibitor or NMDA receptor antagonist), who received at least one prescription and >30 total days supply for any antipsychotic medication, AND who did not have a diagnosis for schizophrenia, bipolar disorder, Huntington's disease, or Tourette's Syndrome.

In line with PQA measure updates for the 2018 measurement year, we will implement an updated methodology for the 2020 display page measures (based on 2018 data) that calculates total days supply. Commenters largely supported this change. One commenter requested additional clarification which was added to the third bullet below.

When calculating a beneficiary's total days supply, the following specifications will be applied:

- Any days supply that extends beyond the end of the measurement period will be excluded,
- In the case of multiple prescription claims with the same date of service, total days supply will only include the supply of the claim with the longest days supply, and
- In the case of multiple overlapping claims for the same target drug with different dates of service, there will be no adjustments for early fills or overlapping days supply (such as moving the prescription start date to the day after the previous fill has ended).

Note, this change also applies to the Use of Opioids at High Dosage (OHD) and Use of Opioids from Multiple Providers (OMP) measures; also Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) measures (See Forecasting to 2021 and Beyond).

Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage Disenrollment Reasons Survey composite measures (Part D). The MA and PDP Disenrollment Reasons Survey asks Medicare beneficiaries who voluntarily disenroll from MA and PDP contracts to report their reasons for disenrollment. Survey responses from disenrollees from MA-PD contracts are combined to create five composite measures of reasons for disenrollment; three of these composites are also calculated for PDP contracts.

CMS assesses the reliability of these composite measures of reasons for disenrollment annually. For many MA-PD and PDP contracts, scores on the Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage composite measures have very low reliability (less than 0.6 on a 0 to 1 scale), meaning that the survey results have low power to distinguish the contract's performance from the national average performance. The low reliability of these measures is primarily due to the relatively small differences between contracts on these categories of reasons for disenrollment.

To strengthen CMS's ability to monitor contract performance and increase the reliability of information provided to beneficiaries and contracts on the Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage measures, CMS will pool the two most recent years of survey data for these composites and their component items for all contracts. That is, each of these composites would include two years of data instead of one. This enhancement is supported by analyses using contracts' 2015 and 2016 data, in which CMS found that adding a second year of data provided adequate reliability (greater than 0.7 on a 0 to 1 scale) to the vast majority of contracts. Plan reports distributed in 2019 based on the 2018 survey fielding would pool 2017 and 2018 survey data to generate the Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage composite measures.

In addition to being reported on the display page, these measures are also reported as drill-downs on Medicare Plan Finder to Members Choosing to Leave the Plan. For new contracts that only have data from the most recent year, the composite measures would be constructed with just that single year of data and be reported to plans and included in the Medicare Plan Finder *only if* the composite's reliability is 0.6 or greater. In that case, the plan report would explain that the score is based on only one year of data, and that in subsequent years two years of data would be combined to calculate the contract's score.

Forecasting to 2021 and Beyond

The following describes potential changes to existing measures and potential new measures for CY 2021 or later. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings for 2021 or later. As we add new measures, CMS will consider which existing measures are topped out or have little variation across contracts to transition them to the display page.

In the CY 2019 Final Rule (CMS-4182-F), we stated that new measures or measures with substantive changes would be proposed through the Federal Register rulemaking process for the 2021 Star Ratings or beyond, while the Advance Notice/Call Letter process would continue to be used for the 2020 Star Ratings. As stated in the CY 2019 Final Rule and codified at § 422.164(c)(2), § 423.184(c)(2), § 422.164(d)(2), and § 423.184(d)(2), new measures and substantive updates to existing measures will be added to the Star Ratings system based on rulemaking; however, CMS will continue to solicit feedback on new measures and measures with substantive updates through the draft Call Letter process.

Health Outcomes Survey (HOS). For the 2019 survey administration, HOS baseline is optional for Institutional Special Needs Plans (I-SNPs) per the HOS measure specifications. CMS proposed to exclude beneficiaries enrolled in I-SNPs at the plan benefit package (PBP) level from HOS Baseline beginning in 2020. Among commenters to the draft Call Letter, there was strong support for the proposed change, and some commenters also recommended that CMS exclude beneficiaries enrolled in all SNP types from the HOS Baseline. Other commenters suggested various methodological changes, including discontinuation of the HOS longitudinal design, reducing the weight of HOS measures, and rewording certain questions to be inclusive of all mental and physical functional limitations. CMS will consider these suggestions as we explore additional enhancements to HOS. As proposed, CMS will exclude beneficiaries enrolled in I-SNPs at the PBP level from HOS Baseline beginning in 2020. Contracts with only one PBP, or with multiple PBPs that are all I-SNPs, are excluded from HOS Baseline. Contracts with at least one non-I-SNP PBP are required to report HOS Baseline if 500 or more enrollees remain after I-SNP enrollees are removed. All MA contracts that reported HOS Baseline in 2018 are required to report HOS Follow-Up in 2020.

Changes to Existing Star Ratings and Display Measures

Plan All-Cause Readmissions (Part C). NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019). The measure assesses the percentage of hospital discharges resulting in unplanned readmissions within 30 days of discharge. The changes made by NCQA are: adding observation stays as hospital discharges and readmissions in the denominator and the numerator, and removing individuals with high frequency hospitalizations. These changes were implemented by the measure steward (NCQA) based on the rise in observation stays to ensure the measure better reflects patient discharge and readmission

volumes. Removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. To date, CMS has only included the 65+ age group in the Plan All-Cause Readmissions measure. CMS is proposing to combine the 18-64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. Given the substantive nature of the proposed updates for this measure, it would be moved to display for the 2021 and 2022 Star Ratings under § 422.164(d)(2). We proposed in the CY 2020 Proposed Rule (83 FR 55022) to return this measure with the substantive updates by the measure steward to the 2023 Star Ratings using data from the 2021 measurement year with, as required by § 422.164(d)(2) and § 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter. We appreciate the comments related to the measure specification, including both the support for the measure and the comments received regarding the specific exclusions and inclusions. All of the comments have been shared with the measure steward, NCQA. A few commenters suggested that the measure specification had not yet been finalized. However, NCQA published in July 2018 the revised specification in Appendix 8 of the HEDIS 2019 Volume 2 Technical Specification for Health Plans.

Medication Reconciliation (Part C). NCQA is considering retiring the standalone Medication Reconciliation Post-Discharge measure from HEDIS. However, information about medication reconciliation will continue to be collected and reported through the Transitions of Care measure, which includes a Medication Reconciliation Post-Discharge indicator. Currently, organizations that use the hybrid method to report the Medication Reconciliation Post-Discharge and Transitions of Care measures may use the same sample for both measures. For the Transitions of Care measure, the medication reconciliation information must be found in the same medical record that is used for reporting the other three indicators in the measure, which should be that of the primary care practitioner or ongoing care provider who is managing the patient's care. Some commenters expressed concern about requiring data to come from the primary care practitioner's or ongoing care provider's medical records. In response to the comments to the draft Call Letter, NCQA will reevaluate the requirements for where the numerator information must be located for the Transitions of Care measure. CMS will continue to use the standalone Medication Reconciliation Post-Discharge measure at this time. Any future changes regarding use of this measure in the Part C Quality Star Ratings program will be addressed in future Call Letters or rulemaking.

Osteoporosis Measures (Part C). NCQA is reevaluating two measures that address osteoporosis in older women. The Osteoporosis Testing in Older Women measure assesses if women 65 and older have ever received a bone mineral density test to screen for osteoporosis, and data are currently collected through a question in the Medicare HOS. This measure is currently on the display page. The Osteoporosis Management in Women Who Had a Fracture measure, which is a current Star Ratings measure, assesses if women age 65 to 85 receive bone mineral density assessment or treatment for osteoporosis after a fragility fracture.

In June 2018 the U.S. Preventive Services Task Force (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/osteoporosis-screening1) updated the recommendation statement for osteoporosis screening. Based on this updated statement, along with updated guidelines from the American College of Physicians https://www.acponline.org/acp-newsroom/american-college-of-physicians-issues-guideline-for-treating-low-bone-density-or-osteoporosis-to), NCQA is proposing[14] several minor changes to the Osteoporosis Management measure. For the denominator, NCQA proposes to update the timing so that members with frailty or those living long-term in an institution during the intake period in the year prior to the measurement year will also be excluded. Currently the measure specification only looks for frailty and long-term institutional care during the measurement year so this non-substantive change would exclude more enrollees from the denominator. Additionally, NCQA proposes to assess all episodes of fracture that occur during the intake period for eligibility to be included in the measure as opposed to assessing only the first episode of fracture. This does not change the intended target population for the measure and members would still only be included once in the measure based on their first eligible episode of fracture. For the numerator, NCQA proposes to remove single-energy X-ray absorptiometry (SEXA) as a test to count as a bone mineral density test after fracture and to remove calcitonin as counting as treatment of osteoporosis. SEXA is considered an outdated technology, and calcitonin is not considered first-line treatment for osteoporosis. NCQA received broad support for these proposed changes during the HEDIS public comment period that was held between February 11 and March 11, 2019. NCQA proposes these changes for HEDIS 2020 which we anticipate treating as non-substantive updates under § 422.164(d) for the 2021 Ratings.

Additionally, NCQA is proposing to retire the Osteoporosis Testing measure, which is currently a display measure, due to validity concerns of using a survey question to accurately assess osteoporosis screening in older women. NCQA plans to explore the development of a new measure that could leverage data from claims, electronic health records, and registries to assess osteoporosis screening. This new measure may be specified to use data according to the Electronic Clinical Data Systems (ECDS) reporting method. If developed and approved, the new measure would likely be included for Medicare reporting in HEDIS 2021. Therefore, NCQA is proposing retirement of the survey-based Osteoporosis Testing measure for HEDIS 2021. CMS has shared all comments received on this measure with NCQA, the measure steward.

Care for Older Adults – Functional Status Assessment Indicator (Part C). NCQA is proposing to refine the hybrid specification for the Functional Status Assessment indicator in the Care for Older Adults measure. Currently, the specification states that documentation of a complete functional status assessment must include (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were

[14] Proposed measure changes will not be finalized until they receive approval by NCQA's Committee on Performance Measurement and Board of Directors in May and June of 2019. Final measure specifications will be available publicly on July 1, 2019, with the next publication of HEDIS.

assessed; (3) result of assessment using a standardized functional assessment tool; or (4) notation that at least three of the following four components were assessed: (a) cognitive status; (b) ambulation status; (c) hearing, vision, and speech; (d) other functional independence (e.g., exercise, ability to perform job). Because the clinical field of functional status assessment is moving toward agreement on assessment using ADLs, IADLs, or another standardized tool, and to improve the clarity of the specification, NCQA is proposing to remove the fourth option for meeting the numerator for this indicator. CMS has shared all comments received on this measure with NCQA, the measure steward. Given the potential impact of removing this fourth option on measure scores, and feedback that NCQA received as part of their public comment period that was held between February 11 and March 11, 2019 that this change may require plans to capture functional status assessment in a different way than previously, NCQA proposes to implement this change for HEDIS 2021 based on the 2020 measurement year. Given the feedback NCQA received, this would be considered a substantive update under § 422.164(d) and the measure would be moved to display for the 2022 and 2023 Star Ratings. We would propose to return it to Star Ratings through future rulemaking.

Hospitalization for Potentially Preventable Complications (Part C). For HEDIS 2020, NCQA is recommending updating the small denominator limit to <150 for all risk-adjusted utilization measures, including Hospitalization for Potentially Preventable Complications, which is a current display measure.

In a future HEDIS revision, NCQA is also considering removing planned hospitalizations on the same admission and discharge date from the numerator, adding a more expansive exclusion for individuals with immunocompromised conditions to the acute measure indicator, and removing the toe amputation exclusion from the chronic measure indicator. NCQA is also considering updates to the risk adjustment model. The exact timing of these changes has not been decided, but they would likely be implemented for HEDIS 2020 or HEDIS 2021. We will evaluate whether these expected changes are substantive or non-substantive under § 422.164(d) to address whether the revised measure will be part of future Star Ratings once the necessary information is available. CMS shared all comments received on this measure with NCQA, the measure steward.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D). Currently, the Proportion of Days calculation (PDC) adjusts for Part D beneficiaries' stays in inpatient (IP) settings for PDPs and MA-PDs, and stays in skilled nursing facilities (SNFs) for PDPs only. The Common Working File (CWF) is the data source for these stays. The days of the relevant stays occurring during the measurement period are essentially removed, or excluded, from the numerator and denominator of the PDC calculation. This is a non-substantive change that benefits the Star Ratings of the sponsoring organizations.

Beginning with the 2019 measurement year for the 2021 Star Ratings, we will include SNF stay data from the CWF if available for MA beneficiaries and MA-PDs. Based on analysis of 2017 data, when applying this adjustment to MA-PDs with available CWF SNF data, there was a negligible overall positive impact to the MA-PD measure rates (0.003% - 0.006%). Section 90.2 Medicare Billing Requirements for Beneficiaries Enrolled in MA Plans in Chapter 6 SNF Inpatient Part A Billing and SNF Consolidated Billing in the Medicare Claims Processing Manual states that SNF providers shall submit a claim to the "fee for service" A/B MAC (A) to subtract benefit days from the CWF records. (Note: The plans do not send claims to CWF for SNF stays). Failure to send a claim to the A/B MAC (A) will inaccurately show days available. All commenters supported this change. Some commenters requested additional information to be able to understand SNF stay adjustment; CMS will investigate what additional information may be feasibly provided to Part D sponsors in the future.

For the future (i.e., 2022 Star Ratings based on 2020 measurement period), we tested using MA encounter data for IP and SNF stays for the PDC adjustment for MA-PDs, in addition to CWF data. Using 2017 data, we evaluated using this additional data source for IP and SNF stays. We found the completeness of encounter data admission and discharge dates to be similar to that of CWF data, and the timeliness of data submissions was adequate. After adding MA encounter data for the IP and SNF stay adjustments for MA-PDs, the overall rates increased slightly for the Diabetes, Hypertension, and Cholesterol Medication Adherence measures (on average by 0.30, 0.43, and 0.55 percentage points, respectively). Although the impact is small, this additional data source improves our ability to identify IP and SNF stays.

The changes discussed above are non-substantive updates under § 422.164 since it adds additional exclusions to the PDC adjustment which narrows the denominator and benefits the sponsors' Star Ratings.

Furthermore, we tested using encounter data to identify beneficiaries with an ESRD diagnosis for exclusion from the Diabetes and Hypertension Medicare Adherence measures for MA-PDs, instead of Risk Adjustment Process System (RAPS) RxHCC data. We simulated this alternative data source for identifying ESRD beneficiaries using 2017 data. The MA-PD rates increased on average by 0.05 and 0.15 percentage points. The impact of removing RAPS RxHCC data as a data source for PDPs was also negligible.

We will test using encounter data to obtain diagnosis code information for other Part D measures (not just the Medication Adherence measures), such as for exclusions. We will provide results from the testing when available. However, due to the complexity and size of these data files, we stated in the draft 2020 Call Letter that we would need to change the frequency of the Patient Safety reports from monthly to quarterly. While most commenters were supportive of using encounter data to improve our ability to identify IP and SNF stays, ESRD beneficiaries, and other exclusions, Part D sponsors overwhelmingly confirmed that they would prefer to continue to receive the Patient Safety reports on a monthly basis for their performance improvement and

monitoring activities. A few commenters suggested that CMS continue to provide the reports on a monthly basis but update the encounter data used in the calculation of the rates in the reports less frequently. CMS concurs with those commenters, and when we add encounter data to the measure calculations as early as the 2020 measurement period, we plan to continue to provide the Patient Safety reports on a monthly basis but update the encounter data quarterly. Note, all final measures and rates will be calculated using complete data.

Antipsychotic Use in Persons with Dementia (APD) and Statin Use in Persons with Diabetes (SUPD) (Part D). The PQA clarified the specifications to state that the eligible population received ≥2 prescription claims on different dates of service. We will apply this non-substantive change to the 2021 measures (based on 2019 data) under § 423.184(d)(1).

Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) (Part D). As discussed in the 2019 Call Letter, we began reporting these measures in the Patient Safety reports for the 2018 measurement year. This was also discussed in the April 6, 2018 HPMS memo, Updates – 2018 Medicare Part D Patient Safety Reports and Overutilization Monitoring System Reports. We described in the draft Call Letter our intent to put these measures on the display page for 2021 and 2022 while we consider rulemaking to add them to the Star Ratings for future years. While there was support in response to the draft 2020 Call Letter to add these measures to the display page, some commenters expressed concern about adding the Poly measures to the Star Ratings. Commenters noted overlap between the two Poly measures and the soon to be retired High Risk Medication measures (see below), and between the Poly-CNS and COB measures. CMS will perform additional data analysis to assess this potential overlap and if the measures are evaluating different concepts. We will share the results in the future. We will add the measures to the display page for 2021 (2019 data) and 2022 (2020 data). Depending on the analysis, we will consider adding all or some of these measures to the 2023 Star Ratings (2021 data), which would be proposed through rulemaking.

Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D). The PQA finalized changes to the three opioid measures for the 2019 measurement year in the 2019 PQA Measure Manual to better align with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain[15] as follows:

Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD): The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) over a period of ≥90 days.

[15] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.

Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.

We tested the revised 2019 PQA measure specifications using 2017 PDE data. The analysis was limited to contracts with more than 30 denominator member-years (M-Y).

Table 16: Distribution of the Revised (2019) Opioid Overuse Quality Metric Rates by Medicare Part D Contract Type, 2017 Data

				Percentiles							
Measure	**Type**	**Count**	**Mean**	**MIN**	**10%**	**25%**	**50%**	**75%**	**90%**	**95%**	**MAX**
OHD	MA-PD	586	7.9%	0.0%	3%	5.4%	7.8%	10.0%	12.7%	15.0%	25.1%
	PDP	58	9.5%	0.4%	4.8%	6.3%	9.3%	11.4%	15.3%	18.2%	30.3%
OMP	MA-PD	586	0.8%	0.0%	0%	0.0%	0.6%	1.1%	2.0%	2.5%	6.8%
	PDP	58	0.6%	0.0%	0%	0.3%	0.5%	0.7%	1.2%	1.5%	1.7%
OHDMP	MA-PD	586	0.1%	0.0%	0%	0.0%	0.0%	0.1%	0.2%	0.4%	2.7%
	PDP	58	0.1%	0.0%	0%	0.0%	0.1%	0.2%	0.2%	0.3%	0.4%

Using these quality metrics that are now better aligned with CDC Guideline recommendations, CMS will be able to better track trends in opioid overuse across the Medicare Part D program and between Part D sponsors, especially high-risk beneficiaries who use 90 MME per day or more. The quality measures are distinct from the other Medicare Part D opioid-related policies, such as opioid safety edits and drug management programs, and may be one way to assess the impact of these efforts (both effectiveness and not impeding appropriate access).

Through the monthly Patient Safety reports, we communicate with plans about their performance on these quality measures, including sharing information about specific beneficiaries identified, and plan sponsors with the worst rating on each measure should report actions they will take to improve performance. Sponsors may use the reports to supplement their drug utilization review (DUR) programs to address overutilization of opioids across a population broader than the Overutilization Monitoring System (OMS) and drug management programs. CMS expects sponsors to routinely monitor these data to compare their performance to overall averages and assess their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.

We will implement these revisions in the Patient Safety reports for the 2019 measurement year and will include all three revised measures on the 2021 display page (2019 data). The majority of commenters supported the revised specifications and adding the measures to the display page. Some comments suggested additional exclusions or specification changes, which we will share with the measures steward (PQA). We will consider rulemaking to include the measures beginning with the 2023 Star Ratings (2021 data).

Note, additional proposals to the Medicare Part D opioid overutilization policy are discussed under the heading "Improving Drug Utilization Review Controls" in the Medicare Part D section.

High Risk Medication (HRM) and Diabetes Medication Dosing (DMD) (Part D). We will retire these two display measures for 2021 and no longer report these measures in the Patient Safety reports for the 2019 measurement year. Commenters supported retiring these two measures.

In response to the draft 2019 Call Letter, some stakeholders expressed concerns about overlap between the HRM display measure and the new Polypharmacy measures. Therefore, we will retire the HRM measure so that sponsors can better focus their resources on the Polypharmacy measures.

The PQA-endorsed DMD measure rate is the percentage of Medicare Part D beneficiaries 18 years or older who were dispensed a dose higher than the daily recommended dose for biguanide, sulfonylurea, thiazolidinedione, and dipeptidyl peptidase (DPP)-IV inhibitor therapeutic classes of oral hypoglycemic drugs. DMD has been a display measure since 2010 (based on 2008 data).

As shown in Table 17, the DMD contract rates were never high, but the rates did decrease almost 70% from 2010 to 2017. Comparison of the 2016 and 2017 Part D contract rate distributions found no significant differences. We believe that the current rates have plateaued. For this reason, we will retire the DMD measure from the 2021 display page and no longer provide Patient Safety reports on this measure for the 2019 measurement year.

Table 17: Diabetes Medication Dosing (DMD) Measure Rates by Part D Contract Type, 2010, 2016 and 2017 YOS

Contract Type	DMD Rate							
	Year	N	Mean	Std Dev	Minimum	Median	95th Pctle	Maximum
MA-PD	2010	552	1.6%	4.5%	0.0%	1.2%	2.9%	98.4%
MA-PD	2016	613	0.7%	2.8%	0.0%	0.3%	1.8%	66.4%
MA-PD	2017	598	0.5%	0.7%	0.0%	0.3%	1.5%	10.3%
PDP	2010	81	1.5%	0.5%	0.0%	1.5%	2.3%	2.9%
PDP	2016	66	0.5%	0.4%	0.0%	0.4%	1.2%	1.6%
PDP	2017	59	0.5%	0.3%	0.0%	0.4%	1.1%	1.2%

Part D sponsors should continue to monitor for prescription fills greater than the daily recommended dose for diabetes medications, as well as, for other high risk drugs using safety edits at the point-of-sale (POS). CMS may also periodically analyze DMD and HRM contract rates to determine if the rates are trending higher and if there is a need to revisit implementation of this or any other retired measure in the future.

Potential New Measure Concepts

Cross-Cutting Topic – Measure Digitalization (Part C). For HEDIS 2020, NCQA is developing digital specifications for up to 20 existing HEDIS Effectiveness of Care measures. The process of converting the measures to a digital format allows for improvements to the HEDIS specifications by providing greater specificity and standardization of the language used to define the measure data elements. These digital specifications will be produced using the Quality Data Model (QDM), clinical quality language (CQL), and standard terminologies and will reference clinical concepts directly instead of using claims-based proxies for measure definitions. Through this effort, NCQA is working to align the HEDIS specifications with provider-level electronic clinical quality measures (eCQMs) wherever possible. These selected digital HEDIS measure packages will be available for HEDIS 2020. In the next year, NCQA will continue this digitalization process, converting another subset of existing HEDIS measures to the digital format. The majority of commenters expressed support for NCQA's efforts moving in the direction of developing digital specifications.

Cross-Cutting Topic – Exclusions for Advanced Illness (Part C). NCQA is continuing work on the advanced illness and long-term care cross-cutting exclusions that were implemented in HEDIS 2019. While HEDIS measures are designed to compare the quality of care provided to general populations or disease-specific care provided to individuals with a chronic condition, measures may not be clinically appropriate for certain individuals with advanced illness and may overlook the quality issues that are specific to these patients. For HEDIS 2020, NCQA is considering expanding the exclusions to allow clinical data to be used to identify individuals with advanced illness and frailty. NCQA is also exploring methods to identify individuals who require nursing home level care who reside in the community. If approved, updates to HEDIS measures for any additional exclusions would be incorporated in HEDIS 2020. CMS will review the updates at that time to determine whether §§ 422.164(d) and 423.184(d) permit incorporation of the updates into the Star Ratings without rulemaking. Commenters to the draft Call letter expressed overwhelming support for these exclusions and suggested additional exclusions that we have shared with NCQA.

Physician/Plan Interactions (Part C & D). In the CY 2019 proposed Part C & D Rule (CMS-4182-P) (82 FR 56336, 56337), CMS solicited and received feedback about conducting a survey of physicians about their interactions with plans on behalf of beneficiaries. Examples of such interactions include their efforts to appeal denials of coverage or to submit claims for payment. Some commenters saw value in a survey, but the vast majority of commenters recommended

against a mandatory survey. Those opposed to the survey cited plan and provider burden, or that results could be skewed for highly integrated plans where physicians only interact with a single plan, many by which they are employed. Among less integrated plans, physicians work with many plans, but most of the interactions plans have are with a centralized staff, not with the physicians themselves. In the draft Call Letter, CMS asked for additional feedback from stakeholders on alternative methods to measure the interactions of providers with plans on behalf of beneficiaries while being mindful of plan and provider burden, and for ways to accurately detect differences between plans. We were particularly interested in receiving feedback on the feasibility of developing and implementing a measure specifically related to plan coverage and payment decisions, claims processing issues, and other common administrative processes that plans have in place. Commenters expressed concerns about implementing any type of physician survey. However, there were some suggestions concerning claims processing timeframes, availability of plan staff to answer physician questions, and ability of physicians to have peer-to-peer interactions with the plan's medical staff. CMS will continue to explore the feasibility of these types of measures for the Star Ratings program.

Interoperability Measures (Part C). Interoperability, the ability of health systems to effortlessly exchange and use electronic health information, is critical to improving care and reducing costs for Medicare beneficiaries. The 21st Century Cures Act defines interoperability as "health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and does not constitute information blocking." CMS sought comment in the draft Call Letter on ways to measure health plans' progress in maximizing their capabilities to exchange health information with other plans, health care providers, and others and to provide beneficiaries access to their health data.

Currently, CMS incentivizes interoperability through the Merit-based Incentive Payment System (MIPS).[16] Through this program, Medicare clinicians are rewarded for meeting benchmarks in care coordination by using certified electronic health record technology (CEHRT) to share test results, visit summaries, and other information with the patient and other health care providers. The Part C and D Star Ratings use "interoperability-sensitive" measures, such the HEDIS Medication Reconciliation Post-Discharge measure and the CAHPS Care Coordination measure. Interoperability-sensitive measures are process and outcome measures impacted by interoperability (exchange and use of electronic health information from external sources). CMS will also be including the interoperability-sensitive HEDIS Transitions of Care measure in the 2020 display measures and is considering it for possible inclusion in the future for Star Ratings.

[16] See https://qpp.cms.gov/mips/overview

CMS asked commenters to provide suggestions for additional measures for MA plans that identify achievements in interoperability and patient access to health data. We asked commenters to consider measurements that address progress towards the adoption of interoperable technology as identified by the Office of the National Coordinator for Health Information Technology (ONC), such as capability for interoperable exchange, the flow and use of interoperable information, and the impacts of interoperability on improving healthcare.[17] Commenters to the draft Call Letter raised concerns regarding the development of interoperability measure when, they stated, the focus should be on setting up the necessary infrastructure. Commenters raised a number of challenges and concerns related to interoperability between plans and providers. Some commenters suggested to measure the presence of tools and technology related to the exchange of information, but others noted that this may be challenging for plans serving underserved communities. CMS will continue to explore potential interoperability measures to add to the Star Ratings. The Star Ratings contractor will solicit feedback from its Technical Expert Panel.

Patient-Reported Outcome Measures (Part C). Patient engagement is key to achieving high quality care. Patients are the ultimate source of information on patient outcomes. Patient-Reported Outcome Measures (PROMs or PROs) have the potential to capture aspects of quality that are best (or perhaps only) assessed by plan members themselves. PROs are widely used in clinical settings to gauge treatment outcomes and increasingly used as global measures to capture health status, quality of life, and other health domains. CMS is considering using new and more targeted PRO measures to hold contracts accountable for the outcomes of care for their members. We asked for feedback and suggestions on PRO measures, including targeted PRO measures and more general ones such as the existing HOS outcome measures.

Currently, CMS assesses two global PRO measures—improving or maintaining physical health and improving or maintaining mental health, both with approximately a two-year window for measured changes. These measures capture information from the patient's point of view and are not specific to a particular disease or condition. Among the more focused topics that have been discussed for PRO measure development are assessments of change in mobility, depression and change in depression over time, patient activation or engagement in the treatment process, physical activity, health-related quality of life, health behaviors (smoking, healthy eating, exercise, etc.), goal achievement, cognitive functioning, pain and how much it interferes with function, sleep quality, and social support. This is not an exhaustive list (the Centers for Disease Control and Prevention (CDC) has more than 1,800 Patient-Reported Outcomes Measurement

[17] See https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf, https://www.healthit.gov/sites/default/files/measurementfinrpt.pdf, and the CMS Interoperability and Patient Access Proposed Rule which introduces new policies that will expand access to health information and improve the seamless exchange of data in healthcare (CMS-9115-P) (https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and).

Information System (PROMIS) measures for use in adults). It should also be noted that information on some of these topics (sleep and depression, for example) are already collected through current patient survey efforts, while others are not reflected in current efforts.

CMS solicited feedback from stakeholders about priorities, challenges, and successes plans have had using similar metrics internally, any synchronicities and/or efficiencies that could be gained from the MA program focusing on particular PROs, and suggestions for future measure development related to PROs. Commenters to the draft Call Letter expressed general support for moving toward more specific PROs and some consistently suggested foci, such as depression, substance abuse, fatigue, mobility and disease-specific measures, although some commenters noted the challenges of collecting PROs and targeting specific populations. Some commenters appreciated recent enhancements to the Health Outcomes Survey (HOS) and made further suggestions. CMS is planning to continue to work on developing new PROs and to enhance the measures used from the Health Outcomes Survey. We will continue to solicit feedback from the industry.

Pain Management (Part C). NCQA is exploring the development of new measures assessing the use of non-opioid therapies (pharmacologic and non-pharmacologic) for pain and PROs (e.g., functional status, quality of life) to manage care for patients with chronic pain. These measures are meant to complement the new opioid overuse measures introduced in HEDIS2018 by evaluating whether patients with chronic pain are receiving appropriate pain management. As a first step, NCQA will hold discussions with plans and practices in the winter/spring of 2019 to assess the use of PROs in pain management. CMS shared all comments received on this measure with NCQA, the measure steward. If approved, these new measures would likely be included in HEDIS 2021. CMS will consider whether to engage in rulemaking to incorporate such new measures into the Star Ratings.

Adherence to Antipsychotic Medications for Individuals with Schizophrenia (Part C). For HEDIS 2020, NCQA is considering expanding the existing HEDIS measure, Adherence to Antipsychotic Medications for Individuals with Schizophrenia, to include reporting for the Medicare health plans. This measure assesses adherence to antipsychotic medication among members with schizophrenia or schizoaffective disorder. Currently, the measure is only specified to assess care delivered to Medicaid enrollees ages 18-64. Testing of the measure in a Medicare claims database in fall of 2018 will allow NCQA to evaluate the feasibility and utility of expanding the measure to include Medicare plans and older adults. If approved, the measure would potentially be reported by MA and cost plans for HEDIS 2020 with possible future reporting on the CMS display page. CMS shared all comments received on this measure with NCQA, the measure steward.

Antibiotic Utilization Measures (Part C). For HEDIS 2020, NCQA is considering expanding three of its existing HEDIS measures to include reporting for the Medicare plans that focus on

antibiotic prescribing practices related to three of the most common acute respiratory conditions for which inappropriate prescribing of antibiotics occurs frequently in the ambulatory care setting. Increased interest and alarm about the overuse of antibiotics led NCQA to consider whether the measures should be broadened to cover more of the population. Clinical guidelines strongly recommend against the use of antibiotics for the treatment of acute bronchitis, upper respiratory infections, and viral pharyngitis, across all age ranges. If approved, the expanded measures would be reported by MA and cost plans for HEDIS 2020 with possible future reporting on the CMS display page. CMS shared all comments received on this measure with NCQA, the measure steward.

Diabetes Overtreatment (Part C). NCQA is exploring the development of a new measure assessing overtreatment in clinically complex, older patients with type 2 diabetes. For certain older adults (e.g., those with multiple comorbidities or functional impairment), there is growing recognition that the harms of pursuing intensive A1c targets may outweigh the benefits – for example, the American Diabetes Association recommends relaxing A1c goals for older adults with multiple coexisting chronic illnesses, cognitive impairment, or functional dependence. This measure would assess whether members are being overtreated (as defined by A1c level and medications). NCQA plans to begin testing this measure in 2019. If approved, this new measure would likely be included in HEDIS 2021. CMS will consider whether to engage in rulemaking to incorporate such new measures into the Star Ratings. CMS shared all comments received on this measure with NCQA, the measure steward.

Removal of Measures from the 2022 Star Ratings

In the CY 2019 Final Rule (CMS-4182-F), CMS codified rules at §§ 422.164(e)(1) and 423.184(e)(1) for removing measures from the Star Ratings program. Under the regulation(s), CMS may remove a measure from the Star Ratings program when:

> (i) the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or
>
> (ii) the measure shows low statistical reliability.

CMS must announce in advance of the measurement period the removal of a measure based upon its application of this regulatory authority to remove a measure from the Star Ratings. The measurement/performance period that will begin after the release of the CY 2020 Call Letter (on April 1, 2019) will be the 2020 measurement year so the earliest CMS could remove the following measures is for the 2022 Star Ratings.

Adult BMI Assessment (Part C). Under § 422.164(e)(1), we will remove the Adult BMI Assessment from the Star Ratings program beginning with the 2020 measurement year and 2022 Star Ratings.

With the introduction of electronic health records, there have been rapid increases in the performance of contracts in this measure with the average performance across contracts increasing from 44% for the 2011 Star Ratings to 98% for the 2019 Star Ratings. Given the significant increase in performance and lack of variation across contracts, the reliability of this measure has declined; therefore, we are removing this measure from the Star Rating program. CMS appreciates the overwhelming support for the removal of this measure from the Star Ratings program as well as from the display page.

Appeals Auto-Forward (Part D), Appeals Upheld (Part D). Under § 423.184(e)(1), we will remove these Part D appeals measures beginning with the 2020 measurement year and 2022 Star Ratings.

CMS has determined that the Part D appeals measures are not statistically reliable. The appeals measures use the data recorded by the IRE as a proxy dataset to evaluate how well a Part D sponsor is processing beneficiaries' requests for coverage determinations and redeterminations. For example, the rate of auto-forwarded cases by enrollment represents a sponsor's untimeliness in making coverage determinations and redeterminations; however, we rely on sponsors adhering to the requirement to identify and send untimely cases to the IRE. Over time, CMS has put into place various methods to evaluate the data integrity of IRE data and safeguard against assigning falsely high ratings to sponsors. CMS is concerned, however, that outside of our data integrity checks, there may be broader issues with the reliability of these measures to evaluate how well Part D sponsors are processing requests for coverage determinations and redeterminations.

As part of our analyses, we want to ensure that we are accurately measuring the Part D appeals processing across contracts. The reliability of a measure decreases with small cell sizes and with low variation across contracts. We have considered both variation in scores across contracts and missing data due to not enough cases to reliably measure performance. Currently, we apply a minimum enrollment threshold for the Appeals Auto-Forward measure, a minimum number of cases reviewed by the IRE for the Appeals Upheld measure in order to address contract size, and we set separate cut points for MA-PDs and PDPs. The minimum number of cases is designed to address reliability issues with the measures.

The reliability of the Part D appeals measures has declined over time, based on standard statistical tests of reliability, defined in the CY 2019 Final Rule as a measure of the fraction of the variation among the observed measure values that is due to real differences in quality rather than random variation. We have not found this pattern to exist with other Star Rating measures, including the Part C appeals measures. It is unclear to CMS how we can improve our ability to reliably measure performance for these measures.

Due to the Part D appeals measures' low reliability, we will remove these measures from the Star Ratings beginning with the 2022 Star Ratings (based on 2020 data). As we cannot remedy the reliability issues, these measures will not be moved to the display page. CMS will stop collection

of Part D Timeliness Monitoring Project (TMP) data after the 2019 data are collected in 2020 for 2021 Star Ratings. CMS will continue to study ideas for ways to monitor Part D access issues and will monitor the current Star Ratings measures that capture Part D access issues, including the Getting Needed Prescription Drugs CAHPS measure and the Complaints measure.

CMS appreciates the feedback from all commenters pertaining to the Part D Appeals measures. CMS continues to monitor sponsors' processing of Part C and D appeals through Part C and D program audits, annual reporting requirements, and other data and operations monitoring activities. We will continue to monitor plans for potential access to care issues and require plans to correct non-compliance by issuing compliance actions (i.e., notices of non-compliance, warning letters, corrective action notices) as well as imposing enforcement actions (i.e., civil money penalties, intermediate sanctions, or contract terminations) when serious or sustained non-compliance is identified.

Measurement and Methodological Enhancements Under Consideration

CMS is exploring the feasibility of testing web options for some existing beneficiary surveys. We appreciate the feedback from plans based on their experiences conducting web surveys with their members. We will continue to explore the feasibility of testing web surveys in conjunction with other methods of survey administration for those members that do not have email or internet access. We will keep plans updated as we move forward with any testing.

Incomplete and Inaccurate Bid Submissions

Incomplete Submissions

Under Sections 1854(a)(1)(A) and 1860D-11(b) of the Act, initial bid submissions for all MA, MA-PD, and PDPs are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY 2020, the bid submission deadline is June 3, 2019 at 11:59 PM Pacific Daylight Time.

The following components are required, if applicable, to constitute a complete bid submission:

- Plan Benefit Package (PBP),
- Bid Pricing Tool (BPT) (if applicable),
- Service Area Verification (SAV),
- Plan Crosswalk (if applicable),
- Cost-Sharing Justification (if applicable, as described in the "Part C Cost Sharing Standards" section of this Call Letter),
- Formulary Submission (if offering a Part D plan with a formulary),
- Formulary Crosswalk (if offering a Part D plan with a formulary); and
- Substantiation (supporting documentation for bid pricing tool).

All MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids, including all required components, are submitted by the June deadline. EGWPs are subject to the submission requirements that have not been waived. If any of the required components are not successfully submitted by the deadline, the bid submission will be considered incomplete and not accepted by CMS absent extraordinary circumstances. This policy is consistent with previous years (for example, please refer to the memo "Release of Contract Year (CY) 2019 Bid Upload Functionality in HPMS," dated May 4, 2018).

The HPMS Bid Upload functionality, which is made available to organizations in May, allows organizations to submit each required bid component well in advance of the deadline. The Bid Upload functionality includes reporting tools that track those components that were successfully submitted and those that are still outstanding. Organizations should take advantage of these resources and make certain all components of their bid are submitted successfully and accurately by the submission deadline.

All organizations are expected to contact the HPMS Help Desk at hpms@cms.hhs.gov about any technical upload or validation errors well in advance of the bid submission deadline. All organizations should make sure appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that might prevent the bid from proceeding to desk review.

Inaccurate Submissions

CMS reminds organizations that it will only approve a Part D bid under 42 C.F.R. § 423.272(b) if the organization offering the plan's bid complies with all applicable Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations. In addition, all Part C bids under 42 C.F.R. § 422.254(a)(3) must be complete, timely, and accurate or CMS may use its authority to impose sanctions or may choose not to renew the contract (see also 42 C.F.R. §§ 422.256 and 423.265). Bids containing inaccurate information and/or that fail to meet established thresholds may, among other things, result in an unnecessary diversion of CMS and organizations' and sponsors' time and call into question an organization's or a sponsor's ability and intention to fully comply with Part C and D requirements. Examples of bids containing information that is clearly inaccurate under Part D requirements and established thresholds are:

- An MA-PD bid that does not offer required prescription drug coverage throughout its service area as required under 42 C.F.R. § 423.104(f)(2) (see also section 20.4.4 of Chapter 5 of the Prescription Drug Benefit Manual),
- A PDP bid for a non-defined standard plan that does not meet the Part D Benefit Parameters set forth in the applicable law and defined benefit thresholds specified in the CY 2020 Call Letter, or
- A Part D bid that includes an incorrect PBP-to-formulary crosswalk.

CMS will issue a compliance notice or request for a corrective action plan to organizations and sponsors that submit clearly inaccurate bids or otherwise violate bidding procedures. Actions triggering such compliance action could include, but are not limited to, the resubmission of bids prior to CMS authorization for bid modification, failure to meet Part C and D requirements, or failure to meet established thresholds. In addition, organizations and sponsors that submit inaccurate bids may not be allowed to revise their bids to correct inaccuracies, and the bids may be denied. Organizations and sponsors should engage in sufficient due diligence to make certain their bids are accurate before submission.

Plan Corrections

As required by 42 C.F.R. §§ 422.254, 423.265(c)(3) and 423.505(k)(4), completion of the final actuarial certification serves as documentation that the final bid, as uploaded, has been verified and is complete and accurate at the time of submission. A request by an organization or sponsor for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's or sponsor's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. A plan correction provides plans with the opportunity to change information in the PBP and must be supported by the BPT. Typos or minor data input errors that do not affect benefits do not need to be submitted as a plan correction. MA organizations are encouraged to conduct a quality review prior to bid submission, and are permitted to make necessary changes during the bid review process to align information in the PBP with the submitted BPT.

After bids are approved, CMS will not reopen the submission gates to correct errors identified by the organization or sponsor until the plan correction window in September. The plan correction window will be open from early September to late September 2019 and the specific dates will be announced in future guidance. The only changes to the PBP that are allowed during the plan correction period are those that modify the PBP data to align with the BPT. No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide organizations and sponsors the guidance and tools necessary for a complete and accurate bid submission. Organizations and sponsors can upload their bid multiple times in HPMS prior to bid submission and can use the HPMS bid reports to verify the accuracy of the submitted bids. Organizations and sponsors are encouraged to use this time prior to the submission deadline to verify their bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance action and may be suppressed in MPF until the first MPF update in November. In addition, CMS may issue more severe compliance actions such as warning letters and requests for corrective action plans to organizations and sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice relating to a plan correction for CY 2019.

We received a few comments stating that CMS should allow more flexibility for correcting simple errors during the plan correction time period due to time constraints throughout the bid review process. We understand the bid review process is challenging from a time and resource perspective and encourage organizations to conduct quality reviews prior to and during the bid review period. CMS permits plans to make changes to the PBP during the bid review process to address these types of concerns prior to bid approval and contract execution. As stated previously, minor errors that do not affect benefits do not need to be submitted as a plan correction.

Innovations in Health Plan Design

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models intended to lower costs while preserving or enhancing quality of care for Medicare, Medicaid, and CHIP beneficiaries. In the 2016 Call Letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries.

In response to these efforts, the Value-Based Insurance Design (VBID) and the Part D Enhanced Medication Therapy Management (MTM) model tests began operations on January 1, 2017. The Part D Payment Modernization Model scheduled to begin on January 1, 2020 with applications currently being accepted. Each of these model tests is described below.

Value-Based Insurance Design (VBID) Model Test

In CY2020, the VBID model is testing whether the additional flexibilities provided under the model allow and incentivize plans to develop and offer interventions that improve health outcomes and lower expenditures for beneficiaries enrolled in participating Medicare Advantage organizations.

Section 50321 of the Bipartisan Budget Act of 2018, "Adapting Benefits to Meet the Needs of the Chronically Ill Medicare Advantage Enrollees," amends section 1859 of the Act to require the Secretary to "revise the testing of the [VBID] model … to cover, effective not later than January 1, 2020, all States." For CY 2020, MA plans in all states and territories that meet model eligibility criteria may apply for participation in the VBID model for one or more VBID component(s). Additionally, all types of Special Needs Plans and Regional Preferred Provider Organizations (RPPOs) may also apply for the model.

For CY2020, the VBID model is testing: (i) Value-Based Insurance Design by Condition, Socioeconomic Status, or Both; (ii) Rewards and Incentives; (iii) Telehealth Networks; and (iv) Wellness and Health Care Planning. Beginning in CY 2021, the VBID model will also test including the Medicare hospice benefit in Medicare Advantage. For more information, including additional details on the model for CY 2020, please visit the VBID model website at https://innovation.cms.gov/initiatives/vbid/.

Part D Enhanced MTM Model

The Part D Enhanced MTM model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. The model is an opportunity for stand-alone basic Part D plans to right-size their investments in MTM services, identify and implement innovative strategies to optimize medication use, improve coordination of care between plans and providers, and strengthen system linkages. Six Part D Sponsors encompassing 22 PBPs are participating in CMS's Part D Enhanced MTM model for 2019. These plans will offer MTM programs subject to the terms and conditions of the model test in the selected regions. All other Part D plans, including any ineligible plans offered by the PDP sponsors of participating plans, will remain subject to the current regulatory requirements for MTM programs. For more information, please visit: https://innovation.cms.gov/initiatives/.

Part D Payment Modernization Model

The President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs called on HHS to increase competition, improve negotiation, create incentives for lower list prices, and reduce out-of-pocket costs. For complete information for how President Trump and Health and Human Services (HHS) Secretary Alex Azar are taking action on lowering drug prices, including downloadable copies of the Blueprint, please visit https://www.hhs.gov/about/leadership/secretary/priorities/drug-prices/index.html.

Through the Part D Payment Modernization model, CMS is executing on the Blueprint and advancing President Trump's commitment to lower prescription drug prices, with Medicare beneficiaries, Part D plans, and CMS all benefiting from a more aligned system.

In January 2020, the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is scheduled to begin the Part D Payment Modernization model to test the impact of a revised Part D program design and incentive alignment on overall Part D prescription drug spending and beneficiary out-of-pocket costs. The model aims to reduce Medicare expenditures while preserving or enhancing quality of care for beneficiaries. The model is open to eligible standalone Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs) that are approved to participate.

This voluntary, five-year model tests the impact of a modernized Part D payment structure that creates new incentives for plans, patients, and providers to choose drugs with lower list prices in order to address rising federal reinsurance subsidy costs in Part D. Eligible standalone Prescription Drug Plans and Medicare Advantage-Prescription Drug Plans that are approved to participate in the model will take two-sided risk for CMS's federal reinsurance subsidy (80 percent of catastrophic phase liability), allowing for performance-based payments to plan sponsors or payments to CMS based on spending. As part of the model, CMS will also provide participants with additional programmatic tools, including a Part D Rewards and Incentives

program, to increase engagement between plans and their enrollees and to promote better enrollee understanding of their Part D benefit, out-of-pocket costs, and clinically equivalent therapeutic options. CMS expects that testing a modernized Part D payment structure will maintain or improve beneficiaries' access to affordable and necessary covered Part D prescription drugs. For more information on the model, please visit the model website at https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/.

Innovative Payment Arrangements in Health Plans

CMS continues to encourage health plans to offer and design innovative payment arrangements with providers, and offers consideration for eligible clinicians that have certain payment arrangements with health plans in the Quality Payment Program All-Payer Combination Option and the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (which started in 2018).

QPP All-Payer Combination Option

As part of the Quality Payment Program (QPP), the All-Payer Combination Option provides APM entities and eligible clinicians an opportunity to achieve QP or partial QP status, if they did not achieve such status through participation in Advanced APMs alone. Through the All-Payer Combination Option, APM entities and eligible clinicians can attain QP or Partial QP status through combined participation in Advanced APMs and Other Payer Advanced APMs. Using the HPMS QPP module, Medicare Advantage plans may submit payment arrangements to determine if they meet the criteria to be Other Payer Advanced APMs. APM Entities and eligible clinicians can then count their participation in an Other Payer Advanced APM toward obtaining QP or Partial QP status. To obtain additional information on submitting Medicare Advantage payment arrangements arrangements for consideration as Other Payer Advanced APMs, go to the QPP website (qpp.cms.gov) Resource Library here: https://qpp.cms.gov/apms/all-payer-advanced-apms.

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

The MAQI Demonstration provides clinicians the opportunity to achieve exclusions from the MIPS reporting requirements and payment adjustment for a given year if they participate to a sufficient degree in Qualifying Payment Arrangements with MAOs, even if they do not participate in an Advanced APM with Medicare.

CMS urges MAOs to assist individual clinicians in responding to the MAQI application. Medicare Advantage plans can submit their payment arrangements through HPMS QPP module to see whether they meet the criteria to be an Other Payer Advanced APM, or work with your clinicians to help them have this information available when they submit through the

MAQI portal. For additional information please visit the MAQI Demonstration website https://innovation.cms.gov/initiatives/maqi/.

Section II – Part C

Overview of CY 2020 Benefits and Bid Review

Portions of this guidance apply to section 1876 cost plans and MA plans (including EGWPs, Dual Eligible Special Needs Plans (D-SNPs), Chronic Condition Special Needs Plans (C-SNPs), and Institutional Special Needs Plans (I-SNPs)).

Medicare-Medicaid Plans in a capitated model under the Medicare-Medicaid Financial Alignment Initiative are not subject to the review criteria summarized in the table below and benefit review guidance for these plans will be provided separately.

CMS makes all of the necessary tools and information available to MA organizations in advance of the bid submission deadline, and therefore expects all MA organizations to submit their best, accurate, and complete bid(s) on or before the Monday, June 3, 2019 deadline. Any organization whose bid fails the Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements at any time prior to final approval will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of error(s).

The following table displays key MA bid review criteria and identifies the criteria used to review the bids of the various plan types identified in the column headings.

Table 18: Plan Types and Applicable Bid Review Criteria

Bid Review Criteria	Applies to Non-Employer Plans (Excluding Dual Eligible SNPs)	Applies to Non-Employer Dual Eligible SNPs	Applies to 1876 Cost Plans	Applies to Employer Plans
Low Enrollment 42 C.F.R. §422. 510(a)(4)(xv)	Yes	Yes	No	No
Total Beneficiary Cost section 1854(a)(5)(C)(ii) of the Act 42 C.F.R. § 422.254	Yes	No	No	No
Maximum Out-of-Pocket (MOOP) Limits 42 C.F.R. §422.100(f)(4) and (5) and §422.101(d)(2) and (3)	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing 42 C.F.R. § 422.254(b)(4) and 422.100(f)(2)	Yes	Yes	No	Yes
Service Category Cost Sharing 42 C.F.R. §§417.454(e), 422.100(f) and 422.100(j)	Yes	Yes	Yes[1]	Yes
Part C Optional Supplemental Benefits 42 C.F.R. §422.100(f)	Yes	Yes	No	No

[1] Section 1876 Cost Plans and MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 C.F.R. §§417.454(e) and 422.100(j)).

CMS has interpreted and applied the regulatory standards for service category cost sharing standards and amounts, PMPM Actuarial Equivalence factors, and TBC requirements for CY 2020 and has provided guidance on these requirements in each applicable section below. Consistent with last year, MA organizations also must address other requirements in their bids, such as the medical loss ratio and health insurance providers' fee, and are expected to do so independently of our requirements for benefits or bid review. Therefore, CMS is not making specific adjustments or allowances for these changes in the benefits review requirements.

Plans with Low Enrollment

At the end of March, CMS notified MA organizations that operate non-SNP plans that had fewer than 500 enrollees and SNP plans that had fewer than 100 enrollees and have been in existence for three or more years as of March 2019 (three annual election periods) of CMS's decision not to renew these plans under 42 C.F.R. §422.510(a)(4)(xv). Plans with low enrollment operating in service areas that do not have a sufficient number of competing options of the same plan type (such that the low enrollment plan still represents a viable plan option for beneficiaries), as

determined by CMS, do not receive this notification. Please note that 42 C.F.R. §422.514 is a minimum enrollment requirement that is applied at the contract level as part of the MA application process and is independent of this plan-level requirement.

Upon receipt of this notification, organizations must either (1) confirm each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2020, or (2) provide a justification to CMS for renewal. If CMS finds that the low enrollment justification is insufficient, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting justifications will be provided in CMS's notification to the organization. These requirements do not apply to Section 1876 cost plans, employer plans, or Medical Savings Account (MSA) plans.

CMS recognizes there may be certain factors, such as the specific populations served by and geographic location of the plan that led to a plan's low enrollment. SNPs, for example, may justifiably have low enrollments because they focus on a subset of enrollees with certain medical conditions. CMS considers this information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MA organizations should follow CMS renewal/non-renewal guidance (see section 50 of Chapter 16B) to determine whether a low enrollment plan may be consolidated with another plan(s). Additional guidance regarding renewal options for 2020 will also be issued in April through HPMS Memo: Information about Renewal Options for 2020). CMS will continue to evaluate and implement low enrollment requirements on an annual basis.

Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Act to deny MA organization bids, on a case-by-case basis, if it determines the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next through the use of the TBC standard. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The methodology for developing the CY 2020 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 21, 2018 titled "Medicare Plan Finder (MPF) Plan Version of Out-of-Pocket Cost (OOPC) Model for CY 2019."

The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. By limiting excessive increases in the TBC from one year to the next, CMS is able to make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases. As in past years, CMS will not evaluate TBC for EGWPs, D-SNPs, SNPs for End Stage Renal Disease (ESRD) Requiring Dialysis, and MSA plans. EGWP benefit packages are negotiated arrangements between

employer groups and MA organizations so we believe that the employer would have taken these costs into account in making such plans available. D-SNP benefits entered into the plan benefit package do not include state benefits and cost sharing relief, which means that a TBC evaluation would not be based on the full benefit and cost sharing package available to enrollees. SNPs for ESRD Requiring Dialysis are not effectively addressed by the OOPC model used for the TBC evaluation and these plans potentially experience larger increases and/or decreases in payment amounts. ESRD SNPs are subject to all other MA standards and CMS will contact plans if CMS identifies large benefit or premium changes (while taking into consideration payment changes) during bid review. Finally, MSAs have unique benefit designs that include a medical savings account for purposes of paying costs below the deductible.

MA plans offering Part C supplemental benefits that take advantage of the flexibility CMS adopted last year in applying the uniformity requirements ("Part C uniformity flexibility") and/or participating in the VBID model test will be subject to the TBC evaluation for CY 2020; however, benefits and cost sharing reductions (entered in Section B-19 of the PBP) that are offered under Part C uniformity flexibility or as part of the VBID model test will be excluded from the TBC calculation. This approach allows CMS to readily evaluate changes in cost sharing and benefits that are provided to all enrollees in a plan.

Under 42 C.F.R. §422.254, CMS reserves the right to further examine and request changes to a plan bid even if a plan's TBC is within the required amount. This approach not only protects enrollees from significant increases in cost sharing or decreases in benefits, but also confirms enrollees have access to viable and sustainable MA plan offerings.

CMS will continue to incorporate the technical and payment adjustments described below and expect organizations to address other factors, such as coding intensity changes, risk adjustment model changes, and payment of the health insurance providers fee independently of our TBC requirement. As such, plans are expected to anticipate and manage changes in payment and other factors to minimize changes in benefit and cost sharing over time. CMS also reminds MA organizations that the Office of the Actuary extends flexibility on margin requirements so MA organizations can satisfy the TBC requirement.

In mid-April 2019, as in past years, CMS will provide plan specific CY 2020 TBC values and incorporate the following adjustments in the TBC calculation to account for changes from one year to the next:

- Technical Adjustments: (1) annual changes in OOPC model software and (2) maximum Part B premium buy-down amount change in the bid pricing tool ($135.50).
- Payment Adjustments: (1) county benchmark, and (2) quality bonus payment and/or rebate percentages.

The TBC change threshold for most plans, as discussed below, will remain at $36.00 PMPM in CY 2020. Therefore, a plan experiencing a net increase in adjustments must have an effective TBC change amount below the $36.00 PMPM threshold to avoid denial of the bid under section 1854(a)(5)(C)(ii). Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the $36.00 PMPM threshold. In an effort to support plans that received increased quality compensation and experience large payment adjustments, along with holding plans accountable for lower quality, CMS will apply the TBC evaluation as follows.

For CY 2020, the TBC change evaluation will be treated differently for the following specific situations:

- Plans with an increase in quality bonus payment and/or rebate percentage, and an overall payment adjustment amount greater than $36.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $36 PMPM) plus applicable technical adjustments.
- Plans with a decrease in quality bonus payments and/or rebate percentage, and an overall payment adjustment amount less than -$36.00 PMPM will have a TBC change threshold of $72.00 PMPM (i.e., 2 times TBC change limit of $36.00 PMPM) plus applicable technical adjustments. That is, plans are not allowed to make changes that result in greater than $72.00 worth of decreased benefits or increased premiums.
- Plans with a star rating below 3.0 and an overall payment adjustment amount less than −$36.00 PMPM will have a TBC change threshold of $72.00 PMPM (i.e., 2 times TBC change limit of $36.00) plus applicable technical adjustments.
- Plans not accounted for in the three specific situations above are evaluated at the $36 PMPM limit, similar to CY 2019.

If CMS provides the MA organization an opportunity to correct CY 2020 TBC issues, following the bid submission deadline, the MA organization cannot change its formulary (e.g., adding drugs, etc.) as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS identified formulary review concerns negatively affects the formulary and bid review process. For example, portions of the annual formulary review process are based on outlier analyses. If an MA organization were permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely impacted. In addition, significant formulary changes will necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor's formulary and could affect approval of its contract. Detailed TBC information and examples will be provided in mid-April 2019 via the HPMS Memorandum titled "CY 2020 MA Bid Review and Operations Guidance."

CMS will maintain the TBC evaluation used during CY 2019 for consolidating or crosswalking plans. CMS will include the operational details of this process in the annual HPMS Memo titled

"CY 2020 Medicare Advantage Bid Review and Operations Guidance," which will be issued in mid-April.

We received some comments that suggested modifications to the TBC evaluation, such as different dollar limits based on rebate percentage and payment changes. Other commenters suggested eliminating the TBC evaluation and finding other ways to maintain cost sharing and benefit stability because in their view, the TBC policy is inconsistent with marketplace dynamics and impedes the ability of plans to respond to changes, such as plan consolidations. These commenters recommended that CMS rely on existing bid review requirements, such as competitive market factors, establishment of maximum cost sharing amounts, and the Medical Loss Ratio (MLR) to evaluate that MA plans are not increasing enrollees' costs or decreasing their benefits too drastically. Several commenters opposed eliminating the TBC evaluation because the requirement protects beneficiaries from unexpected changes in benefits and/or premium. Other commenters expressed concern that new supplemental benefit flexibilities are not incorporated into the OOPC calculation and that as a result, the TBC may not be representative of the overall benefit package. Other commenters stated that TBC should be adjusted for the proposed safe harbor rule that may result in higher premiums and/or reduced benefits for MA plans. Several commenters stated that CMS should improve beneficiary decision-making resources, such as providing more detailed information about supplemental benefits provided by each plan on MPF, including those benefits resulting from new flexibilities provided by CMS.

We appreciate the comments and suggested alternatives and will continue to evaluate recommendations from comments submitted to the draft CY 2019 and CY 2020 Call Letters and we plan to explore alternatives to the current TBC evaluation for future years, including whether various potential changes may require rulemaking. CMS will finalize the TBC threshold for most plans at $36.00 PMPM for CY 2020. In addition, we will communicate suggestions for MPF enhancements to the appropriate CMS components.

Maximum Out-of-Pocket (MOOP) Limits

Under 42 C.F.R. §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), all MA plans, including employer group plans and SNPs, must establish limits on enrollee out-of-pocket cost sharing (i.e., deductibles, coinsurance, and copayments) for Parts A and B services that do not exceed the annual limits set by CMS. In setting these limits under the regulation, CMS uses Medicare Fee-for-Service data to strike a balance between limiting maximum beneficiary out-of-pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. This standard was adopted in the recent final rule Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-F) (83 Fed. Reg. 16440 (Apr. 16,

2018)) and is applicable no earlier than January 1, 2020. As we are setting the limits for coverage beginning January 1, 2020, the new regulatory standard is applicable.

Local and regional PPO plans are required to have two MOOP limits established by CMS, including (a) an in-network and (b) a catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. HMO-POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or to a combined in- and out-of-network MOOP limit. Although the MOOP requirement is for Parts A and B services, an MA organization can include supplemental benefits as services that are subject to the MOOP. MA plans may establish as their MOOP any amount within the ranges shown in table 19.

Table 19 below displays the CY 2020 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to Local PPOs and Regional PPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing. The possible ranges of the MOOP amount within each plan type are displayed in order to illustrate that MOOP limits may be lower than the CMS-established maximum amounts and what MOOP amounts qualify as mandatory and voluntary MOOP limits. As clarified in previous Call Letters, the in-network MOOP amount dictates the combined MOOP range for PPOs (i.e., PPOs are not permitted to offer a combined MOOP amount within the mandatory range, while having an in-network MOOP amount within the voluntary range).

Table 19: CY 2020 Voluntary and Mandatory MOOP Range Amounts by Plan Type

Plan Type	**Voluntary**	**Mandatory**
HMO	$0 - $3,400	$3,401 - $6,700
HMO POS	$0 - $3,400 In-network	$3,401 - $6,700 In-network
Local PPO	$0 - $3,400 In-network and $0 -$5,100 Combined	$3,401 - $6,700 In-network and $3,401 - $10,000 Combined
Regional PPO	$0 - $3,400 In-network and $0 - $5,100 Combined	$3,401 - $6,700 In-network and $3,401 - $10,000 Combined
PFFS (full network)	$0 - $3,400 Combined	$3,401 - $6,700 Combined
PFFS (partial network)	$0 - $3,400 Combined	$3,401 - $6,700 Combined
PFFS (non-network)	$0 - $3,400	$3,401 - $6,700

MOOP limits are based on a Medicare FFS data by using the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. Actual data for Parts A and B services are based on claims from the National Claims History files. The Office of the Actuary conducted an analysis to help determine the proposed MOOP amounts by projecting

cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and Original Medicare. To minimize beneficiary disruption, the mandatory MOOP amount will continue to represent approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, five percent of Original Medicare beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments and coinsurance. The voluntary MOOP amount of $3,400 will continue to represent approximately the 85th percentile of projected Original Medicare out-of-pocket costs. Although CMS has the authority to adjust MOOP limits annually, based on changes in market conditions and to ensure the sustainability of the MA program and benefit options, we intend to transition changes over time to avoid disruption to benefit designs and minimize potential beneficiary confusion. In addition, we intend to continue communicating MOOP limit changes through the annual Call Letter process to allow for public comment and MA organizations to plan and prepare bid submissions.

Although most dually eligible enrollees are not responsible for paying cost sharing, certain D-SNPs (Medicare Non-Zero-Dollar Cost Sharing Plans) enroll dually eligible enrollees who do pay cost sharing. Any dually eligible enrollee exempted from cost sharing who loses his/her Medicaid eligibility may be responsible for cost sharing for the period he/she has lost Medicaid coverage, and remain enrolled in the D-SNP. This also applies to Medicare Zero-Dollar Cost Sharing Plans that apply cost sharing in their Medicare Part A and B benefit package but enroll only dually eligible individuals who are exempt from cost sharing.

D-SNPs have the flexibility to establish zero dollars as the MOOP limit, thereby guaranteeing there is no cost sharing for enrollees, including those who are liable for Medicare cost sharing. Otherwise, if the D-SNP does apply cost sharing for Medicare Part A and B covered benefits, then it must track enrollees' out-of-pocket spending, and it is up to the plan to develop the process and vehicle for doing so.

Commenters supported the MOOP limits and a few commented that CMS should include Part D out-of-pocket costs in the MOOP as an additional beneficiary protection. Another commenter stated that plans should be required to include supplemental benefits in the MOOP limits. We note that some of these suggestions, such as including Part D or supplemental benefits in the MOOP limits, would require rulemaking. CMS is finalizing the MOOP limits for CY2020 without change. We will consider the comments received as we evaluate MOOP in future years. We remind commenters that the MOOP limits are set pursuant to regulations at §§ 422.100(f) and 422.101(d).

Per Member Per Month (PMPM) Cost Sharing Limits to Address Actuarial Equivalent (AE) Cost Sharing Limits and Anti-Discrimination Standards

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis[18] and must not be discriminatory. In order to ensure that cost sharing is consistent with both 42 C.F.R. §422.254(b)(4) and §422.100(f)(2) and (6), CMS will evaluate actuarial equivalent cost sharing limits separately in the following service categories for CY 2020: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. Please note that factors for Inpatient and SNF in column #4 of the table below (Part B Adjustment Factor to Incorporate Part B Cost Sharing) have been updated for CY 2020.

Whether in aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the BPT. Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to Original Medicare Actuarially Equivalent (AE) Cost Sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing. Therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

Once the comparison amounts have been determined, excess cost sharing can be identified. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1) and the comparison amount (column #5). The table below uses illustrative values to demonstrate the mechanics of this determination.

[18] MA plans may establish lower cost sharing as a mandatory supplemental benefit. See 42 C.F.R. §§ 422.2 (definition of mandatory supplemental benefit) and 422.102(a)(4).

Table 20: Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	**PMPM Plan Cost Sharing (Parts A&B)** ***(BPT Col. l)***	**Original Medicare Allowed** ***(BPT Col. m)***	**Original Medicare AE Cost sharing** ***(BPT Col. n)*** [1]	**Part B Adjustment Factor to Incorporate Part B Cost Sharing (Based on FFS data)**	**Comparison Amount** ***(#3 × #4)***	**Excess Cost Sharing (#1 − #5, min of $0)**	**Pass / Fail**
Inpatient	$33.49	$331.06	$25.30	1.390	$35.18	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.068	$10.57	$0.26	Fail
DME	$3.00	$11.37	$2.65	1	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1	$0.33	$0.00	Pass

[1] PMPM values in column #3 for Inpatient and Skilled Nursing Facility only reflect Part A fee-for-service actuarial equivalent cost sharing for that service category.

NOTE: Beginning in CY 2017, CMS waived the requirement for MA employer plans to submit a Bid Pricing Tool (BPT), which affects our ability to evaluate the PMPM Actuarial Equivalent Cost Sharing discussed in this section. MA employer plans continue to be subject to all unwaived MA regulatory requirements regardless of whether they are affirmatively evaluated as part of bid review or in connection with other reviews.

Part C Cost Sharing Standards

For CY 2020, CMS will continue the current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. Table 21 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for MA plans that we will not consider discriminatory or in violation of other applicable standards. Pursuant to § 422.100, CY 2020 bids must reflect enrollee cost sharing for in-network services no greater than the amounts displayed below. These standards will be applied only to in-network Parts A and B services unless otherwise indicated in the table. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. Inpatient and Skilled Nursing Facility (Days 21 through 100) standards have been updated to reflect estimated changes in Original Medicare cost for CY 2020.

As noted in the draft Call Letter, CMS has monitored and required MA organizations to provide justification for cost sharing above certain thresholds for cardiac rehabilitation and pulmonary rehabilitation in past years and sought comment on adding standards in the PBP for these and

other categories. Commenters supported adding cost sharing standards in section B-3 of the PBP for cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, and supervised exercise therapy (SET) for peripheral artery disease (PAD) services for CY 2020. Please note that CMS will have separate PBP data entry for SET for PAD for CY 2020.

Table 21: CY 2020 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient Hospital – Acute - 60 days	1a	N/A	$4,777
Inpatient Hospital – Acute - 10 days	1a	$2,721	$2,177
Inpatient Hospital – Acute - 6 days	1a	$2,461	$1,969
Inpatient Hospital Psychiatric - 60 days	1b	$3,048	$2,438
Inpatient Hospital Psychiatric - 15 days	1b	$2,204	$1,763
Skilled Nursing Facility – First 20 Days[1,2]	2	$20/day	$0/day
Skilled Nursing Facility – Days 21 through 100[1,2]	2	$178/d	$178/d
Cardiac Rehabilitation	3	$50	$50
Intensive Cardiac Rehabilitation	3	$100	$100
Pulmonary Rehabilitation	3	$30	$30
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)	3	$30	$30
Emergency Care/Post Stabilization Care[3]	4a	$120	$90
Urgently Needed Services[3]	4b	$65	$65
Partial Hospitalization	5	$55/day	$55/day
Home Health	6a	20% or $35	$0
Primary Care Physician	7a	$35	$35
Chiropractic Care	7b	$20	$20
Occupational Therapy	7c	$40	$40
Physician Specialist	7d	$50	$50
Psychiatric and Mental Health Specialty Services	7e and 7h	$40	$40
Physical Therapy and Speech-language Pathology	7i	$40	$40
Therapeutic Radiological Services	8b	20% or $60	20% or $60
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10
Dialysis Services[1]	12	20% or $30	20% or $30
Part B Drugs-Chemotherapy[1,4]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

[1] MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services (42 CFR §§ 417.454(e) and 422.100(j)).

[2] MA plans that establish a voluntary MOOP may have cost sharing for the first 20 days of a SNF stay. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).

[3] Emergency Care and Urgently Needed Care benefits are not subject to plan level deductible amount and/or out-of-network providers. The dollar amount included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance).

[4] Part B Drugs - Chemotherapy cost sharing displayed is for services provided on an outpatient basis and includes administration services.

MA organizations have the option to charge either coinsurance or a copayment for most service category benefits. For example, based on the cost sharing requirements indicated above for Part B Drugs – Chemotherapy, a plan can choose to either assign up to a 20% coinsurance or $75 copayment to that particular benefit. MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services (42 C.F.R. § 422.100(j)). Although CMS has not established a specific service category cost sharing limit for all possible services, CMS has a longstanding interpretation of the anti-discrimination provisions that payment of less than 50% of the contracted (or Medicare allowable) rate and use of cost sharing for services that exceeds 50% of the total financial liability for the benefit discriminates against enrollees who need those services. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Original Medicare service category cannot exceed 50% of the average contracted rate of that service (Medicare Managed Care Manual, Chapter 4, Section 50.1).

Copayments are expected to reflect specific benefits identified within the PBP service category or a reasonable group of benefits or services provided. Some PBP service categories may identify specific benefits for which a unique copayment would apply (e.g., category 7a includes primary care services), while other categories include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (e.g., category 8b includes outpatient diagnostic radiological services).

MA organizations with benefit designs using a coinsurance or copayment amount for which CMS does not have an established threshold for non-discriminatory cost-sharing (e.g., coinsurance for inpatient or copayment for durable medical equipment) must submit documentation with their initial bid that clearly demonstrates how the coinsurance or copayment amount satisfies the regulatory requirements, as interpreted and implemented here, for each applicable plan. This documentation may include information for multiple plans and must be identified separately from other supporting documentation submitted as part of the BPT. The documentation must be submitted for each plan through the supporting documentation upload section titled "Cost-Sharing Justification" in HPMS. The upload will be available to all MA plan

types (both employer and individual market), but not for stand-alone PDPs. The link for uploading cost sharing justification files will be located at Plan Bids > Bid Submission > CY 2020 > Upload > Cost-Sharing Justification.

CMS annually evaluates available Medicare data and other information to apply MA requirements in accordance with applicable law. Organizations are afforded the flexibility to design their benefits as they see fit so long as they satisfy Medicare coverage requirements. We remind organizations that they also must comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex, age or disability, including Section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

In addition to supporting our proposal for CY 2020, some commenters recommended CMS reduce the thresholds used in evaluating the cost sharing for repetitive services, such as pulmonary rehabilitation and physical therapy. Commenters asked that CMS be mindful of the frequency of visits an enrollee may experience over an extended period of time and to consider allowing plans to design benefits with one cost sharing amount for multiple visits provided during an episode of care. Some commenters expressed support that the threshold for cost sharing for emergency care was maintained for CY 2020 and urged CMS to continue to maintain or decrease cost sharing for emergency services in future years. Commenters expressed concern about the impact that cost sharing for emergency services may have on enrollees and how this burden may serve to deter enrollees from seeking emergency care services.

CMS will finalize the cost sharing standards without change. We appreciate these comments and suggestions and will consider them for future years. We note that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care, providing the cost sharing amount satisfies CMS standards.

Part C Optional Supplemental Benefits

As part of our evaluation to ensure a plan's bid and benefits do not discriminate against enrollees with specific (or high cost) health needs, CMS will review non-employer MA plans' bid submissions to verify that enrollees electing optional supplemental benefits are receiving reasonable value at the MA contract level. CMS considers plan designs for optional supplemental benefits to be non-discriminatory when the total value of the optional supplemental benefits offered by all plans under the contract meet the following thresholds: (a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15% and (b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by a percent of premium, is no greater than 30%.

CMS understands some supplemental benefits are based on a multi-year projections, but the plan bids submitted each year are evaluated based on that particular plan year.

Medicare-covered Opioid Treatment Program Services Beginning in CY 2020

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115-271) (the SUPPORT for Patients and Communities Act) establishes opioid use disorder treatment services furnished by Opioid Treatment Programs (OTPs) as a Medicare Part B benefit beginning January 1, 2020. Opioid use disorder treatment services include: FDA-approved opioid agonist and antagonist treatment medications and the dispensing and administration of such medications, if applicable; substance use counseling; individual and group therapy; toxicology testing; and other items and services that CMS determines appropriate (not to include meals and transportation). For Medicare coverage and payment, OTPs must be enrolled in Medicare, certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), accredited by a SAMHSA-approved entity, and meet any additional requirements that CMS determines are necessary for health and safety and to ensure the effective and efficient furnishing of opioid use disorder treatment services. Medicare Health plans including all MA plan types (HMO, LPPO, RPPO, PFFS, MSA), Section 1876 & Section 1833 cost-based plans, and PACE organizations will be required to provide opioid use disorder treatment services as a Medicare-covered benefit and must enter cost sharing for OTP services in PBP service category B7k as appropriate.

Plans must provide enrollees with a level of access to Medicare-covered services that is consistent with prevailing community patterns of care in the areas where the network is being offered (§ 422.112(a)(10)).

Most commenters expressed a desire to receive timely guidance about bid preparations, providers and networks, benefits, drug policy and compliance.

Commenters requested information on how CMS would factor the need for Medicare-enrolled OTPs into our evaluations of the adequacy of plans' provider networks, when CMS would enroll OTPs, and where plans could locate the list of enrolled OTPs. Some commenters requested CMS extend the deadline by which OTP providers needed to be enrolled in Medicare by one year. Commenters requested that CMS provide sufficient time for plans to enter into contracts with OTPs and consider that an OTP's capacity may be limited. Others requested that CMS allow mental health professionals or other professionals authorized under state law to be recognized as OTPs and be allowed to provide substance use disorder counseling, as well as individual and group therapy to Medicare enrollees. Another commenter asked whether offering opioid use disorder treatment services through additional telehealth benefits would satisfy CMS's network adequacy requirements.

Commenters requested CMS provide information about opioid use disorder treatment benefits, including a list of Medicare approved services, benefit minimums and maximums, clinical guidelines and medical necessity criteria (e.g., authorization requirements and appeals/grievance

processes). Other commenters suggested that CMS educate beneficiaries and providers about the availability of the OTP benefit.

Commenters requested that CMS clarify how coverage of opioid agonist and antagonists would work with different plan types (e.g., MA-only plans and EGWP designs that have stand-alone PDP plans) and how CMS would treat drugs dispensed by OTPs (Part B vs. Part D). Commenters also requested clarification about whether the benefit would coordinate with Part D requirements and if prescribers who are not part of an OTP, but are Drug Addiction Treatment Act of 2000 (DATA 2000) certified,[19] will be able to continue to prescribe and provide Medication Assisted Treatment (MAT) services.

Commenters supported CMS's requirements that plans must provide enrollees with a level of access to OTP-provided Medicare-covered services that is consistent with prevailing community patterns of care in the areas where the network is being offered. A commenter requested that the compliance mechanism by which CMS would ensure that plans provide equivalent coverage be made known to the public.

CMS clarifies that buprenorphine prescribed by DATA 2000 providers outside of OTPs can continue to be covered under Part D. The DATA 2000 and OTP programs are designed to meet the needs of those needing opioid dependency treatment in different ways[20]. Therefore, because buprenorphine is still covered under Part D when furnished outside an OTP, sponsors should not need to implement new point of service Part B vs. Part D pharmacy edits for a buprenorphine claim. CMS will provide additional guidance about this new Part B benefit, including how to arrange for services, as it becomes available. MA organizations should prepare their bids using available information and may submit pricing questions to the Office of the Actuary prior to bid submission. We reiterate that MA plans must provide all medically necessary Part A and Part B covered services to enrollees consistent with section 1852 of the Act and the regulations in part 422.

Non-Opioid Pain Management Supplemental Benefits

CMS encourages MA organizations to consider Part C benefit designs for supplemental benefits that address non-opioid pain management and complementary and integrative treatments. For example, "peer support services" delivered by qualified individuals may be effective in facilitating recovery and assist in navigating health care resources as part of pain management treatment. For purposes of completing the PBP, peer support services can be included in counseling services (PBP 14c). In addition, non-Medicare covered chiropractic services (PBP 7b), acupuncture (PBP 13a), fitness benefit (PBP B14c) and therapeutic massage (PBP B14c) furnished by a state licensed massage therapist, may also be incorporated into plan designs.

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[19] Information about the Drug Addiction Treatment Act of 2000 (DATA 2000) can be found at https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines#DATA-2000.

[20] See https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver.

"Massage" should not be singled out as a particular aspect of other coverage (e.g., chiropractic care or occupational therapy) and must be ordered by a physician or medical professional, as defined by the plan, in order to be considered primarily health related and not primarily for the comfort or relaxation of the enrollee. The non-opioid pain management item or service must treat or ameliorate the impact of an injury or illness (e.g., pain, stiffness, loss of range of motion).

Commenters supported MA organizations incorporating Part C supplemental benefits that address non-opioid pain management and complementary and integrative treatments as part of their benefit designs. Several commenters noted that plans should not restrict access to opioid-based pain management services when medically necessary (e.g., hospice and spinal injuries). Commenters also emphasized the need for organizations to incorporate Medicare-covered services along with supplemental benefits as an overall approach to manage non-opioid pain management. Some commenters stated that plans should examine their coverage and utilization management policies for non-pharmaceutical pain management treatments (e.g., physical therapy) to ensure they are not promoting an over-reliance on opioids for pain management, instead of supporting multimodal pain care. A commenter recommended CMS provide timely guidance on what is considered an acceptable evidence-based peer support program. Other commenters suggested CMS include additional language in the final Call Letter that explicitly states which providers are authorized to provide non-opioid pain management supplemental benefits.

CMS agrees that medically necessary opioid therapy is appropriate when other options are not available and notes that our guidance is focused on complementary and integrative non-opioid treatments for effective pain and symptom management. At times these treatments may be stand alone and at other times they may be adjunctive or meant to reduce the amount of opioids needed. Medicare-covered services (e.g., physical therapy) along with supplemental benefits (which are not covered by Medicare) can be part of an overall non-opioid pain management strategy, including as described in the work of the HHS Pain Management Inter-Agency Task Force. CMS encourages organizations to evaluate coverage and utilization management policies to ensure they are not inadvertently promoting opioids or any other particular medication or therapies for pain management, instead of supporting multimodal pain care. MA organizations should refer to the Substance Abuse and Mental Health Services Administration (SAMHSA) website for information about peer support services that could be included in a supplemental benefit. With regard to comments about the use of appropriate providers, we remind MA plans of that § 422.204 imposes limits on which providers may be used to furnish original Medicare benefits: basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare. Further, the process used by MA organizations to select and credential network providers must ensure that providers

are licensed or certified, as applicable, in the state in which they practice. 42 C.F.R. § 422.204(b). We also note that MA, cost and PACE plans are required to follow the preclusion list requirements under which they may not pay providers or suppliers who are precluded as established in the MA regulations at §§ 422.222 and 422.224.

Potential Changes to MOOP and Cost Sharing Standards for CY 2021

CMS requested comments and suggestions on its application and interpretation of MOOP and cost sharing standards for CY 2021 and subsequent years. As discussed in the draft Call Letter, under 42 C.F.R. §§ 422.100(f)(4), (5), and (6), and 422.101(d)(2) and (3), as revised in the final rule (CMS-4182-F) issued April 16, 2018, CMS has the authority to: (1) increase the voluntary MOOP limit to another percentile level of Medicare FFS; (2) increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount; and (3) implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits.

For CY 2021, CMS is considering whether to establish a third MOOP limit (referred to as the intermediate MOOP limit) that would be the approximate numeric midpoint between the mandatory and voluntary MOOP limits for the applicable year (i.e., mandatory MOOP limit, less approximately 50% of the numeric difference between the mandatory and voluntary MOOP amounts). As explained in the draft Call Letter, CMS expects that implementing more than two levels of MOOP and cost sharing limits would encourage plan offerings with lower MOOP limits and result in more favorable benefit designs for beneficiaries.

The percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7% in CY 2011 to 71.0% in CY 2018. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51.2% in CY 2011 to 22.8% in CY 2018. Although the MA program experienced a small increase in access and enrollment in plans with the lower, voluntary MOOP limit between 2017 and 2018, we believe it is important to maintain the lower MOOP limit near the existing $3,400 limit. As discussed earlier in this Call Letter, the Office of the Actuary conducted an analysis to help CMS determine the proposed MOOP amounts by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and Original Medicare. The current voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs and CMS may adjust the percentile level accordingly for CY 2021 to maintain the lower MOOP limit at or very near the existing $3,400 limit. This approach is consistent with the regulatory standard of striking an appropriate balance between limiting beneficiary out-of-pocket costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages.

The table below illustrates the three MOOP limits (using current information to provide examples) that we are considering for application and interpretation of the standards in §§ 422.100(f) and 422.101(d) beginning in 2021.

Table 22: Proposed CY 2021 MOOP Limits and Examples

MOOP Limit	Approximate Original Medicare Percentile	Examples Based on Current MOOP limits	
		In-network	Combined In- & Out-of Network
Mandatory	95th	$5,001 to $6,700	$7,501 to $10,000
Intermediate	Approximate numeric midpoint*	$3,401 to $5,000	$5,101 to $7,500
Lower	85th	$0 to $3,400	$0 to $5,100

* The intermediate MOOP limit would be based on the mandatory MOOP limit, less approximately 50% of the numeric difference between the mandatory and voluntary MOOP amounts.

CMS is also considering additional flexibilities for the service category cost sharing standards described below for MA plans that elect to use the intermediate MOOP or the lower MOOP. These changes would afford such MA plans that adopt the lower or intermediate MOOP limits greater flexibility in establishing Parts A and B cost sharing than is available to MA plans that adopt the higher, mandatory MOOP limit. Flexibilities under consideration include:

- Adding one or two additional inpatient length of stay scenarios for both acute and psychiatric care. The cost sharing standard for mandatory and lower voluntary MOOP limits would continue to be based on 100% and 125% of estimated Medicare FFS cost sharing, respectively. The intermediate MOOP limit cost sharing standard would be based on the approximate mid-point between the mandatory and lower voluntary cost sharing limits. (We note that overall MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis.)

- Establishing nominal cost sharing limits during the first 20 days of a SNF stay for both lower and intermediate voluntary MOOP limits. Per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount, and total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to section 1852(a)(1)(B). For example, the per-day cost sharing limit during the first 20 days of a SNF stay could be $0 for mandatory, $10 for intermediate, and $20 for the lower MOOP limits, so long as the overall actuarial equivalence for the SNF benefit is met.

- Varying cost sharing limits across all three proposed MOOP limits for emergency care/post stabilization care (PBP B4a), home health services (PBP B6a), and physician specialist services (PBP B7d). We intend to include varying cost sharing across additional services in future years as part of this flexibility.

- Introducing new cost sharing limits for observation services (PBP B9a) and ambulance services (PBP B10a) that would use the same cost sharing across all three MOOP limits for CY 2021. As previously stated, we may vary cost sharing for these two services in future years as part of this flexibility.

Most commenters supported moving forward with the MOOP limits CMS outlined for use in CY 2021. One organization suggested delaying this specific application and implementation of the cited regulations because the MA program will experience significant changes in 2021, such as plans enrolling ESRD patients, the hospice carve-in payment and service model conducted as part of the VBID model, and the recently proposed safe harbor rule. A commenter expressed concern that, unlike original Medicare, CMS permitting MA plans to have nominal cost sharing during the first 20 days of a SNF stay may shift costs to the enrollees and result in bad debt for SNF providers. Some commenters expressed concern about adding another level of complexity to plan offerings at a time when the MA program is undergoing significant change.

We appreciate these comments and suggestions and will consider them as we develop our approach for applying and implementing §§ 422.100(f) and 422.101(d) for CY 2021 and future years. CMS will continue to evaluate MOOP limits in light of programmatic changes, such as ESRD beneficiaries enrolling in MA plans beginning in CY 2021, which may impact MOOP limits in future years. In light of this, CMS intends to transition changes over time to minimize disruption.

Supplemental Benefit Clarifications

CMS received feedback requesting clarification about whether specific items and services are considered permissible primarily health related supplemental benefits. In implementing the authority for MA plans to offer supplemental benefits, whether mandatory or optional benefits, CMS has historically interpreted section 1853(a)(3) of the Act as requiring (the following criteria for the an item or service: (1) it is not covered by Original Medicare, (2) it is primarily health related, and (3) the plan must incur a non-zero direct medical cost in furnishing or covering it. An item or service that meets all three conditions may be proposed for all enrollees, subject to guidance in the final CY 2019 Call Letter regarding flexibility in providing uniform benefits, as a supplemental benefit in a plan benefit package (PBP). See Chapter 4 of the Medicare Managed Care Manual, § 30.1 for additional guidance. Beginning in CY 2019, CMS expanded its interpretation of the criterion that supplemental benefits be “primarily health related” to consider an item or service as primarily health related if it is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health

conditions, or reduces avoidable emergency and healthcare utilization. A supplemental benefit is not primarily health related if it is an item or service that is solely or primarily used for cosmetic, comfort, or general use purposes.

The following are examples of primarily health related non-Medicare covered items and services that are allowable supplemental benefits and where information should be entered and briefly described in the PBP (this list is not exhaustive):

- Compression garments as part of an over-the-counter benefit (PBP 13c)
- Cooking classes as part of a nutritional/dietary or health education benefit (PBP 14c)
- Fall prevention kits as part of home & bathroom safety devices (PBP 14c)
- Implantable hearing aids, such as middle ear implants as part of a hearing benefit (PBP 18b)

Special Supplemental Benefits for the Chronically Ill (SSBCI)

In last year's Call Letter, CMS expanded its interpretation of how a benefit may be a "health care benefit" that is approvable as a supplemental benefit offered by an MA plan under section 1852(a)(3) of the Act; CMS has historically interpreted the statute as requiring a supplemental benefit to (1) not be covered by Original Medicare, (2) be primarily health related, and (3) require the MA plan to incur a non-zero direct medical cost. Specifically, CMS expanded its definition of "primarily health related" to consider items or services used to "diagnose, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization."

Separately, the Bipartisan Budget Act of 2018 (Pub. L. 115-123) amended section 1852(a) of the Act to further expand the types of supplemental benefits that may be offered by Medicare Advantage plans to chronically ill enrollees. We refer to these as Special Supplemental Benefits for the Chronically Ill (SSBCI). SSBCI include supplemental benefits that are not primarily health related and may be offered non-uniformly to eligible chronically ill enrollees, as discussed below. We believe the intended purpose of the new category of supplemental benefits is to enable MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for the chronically ill population.

Section 1852(a)(3)(D)(ii), as amended, defines a chronically ill enrollee as an individual who:

1) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
2) has a high risk of hospitalization or other adverse health outcomes; and
3) requires intensive care coordination.

In the draft Call Letter, CMS solicited comment on whether plans should have flexibility to determine what is a medically complex chronic condition that meets the statutory standard ("is life threatening or significantly limits the overall health or function of the enrollee") and if CMS

should consider alternative approaches to determining what meets this criterion. The majority of comments were supportive of our proposal in the draft Call Letter to allow MA plans to identify chronically ill individuals that meet the above definition using the current list of chronic conditions listed in chapter 16b. Some commenters requested CMS allow plans greater flexibility to determine what is a chronic condition but did not suggest specific conditions outside of the current list of chronic conditions listed in chapter 16b.

We note that a large percentage of the current Medicare Advantage population (about 73%) have one or more chronic conditions on the list of chronic conditions in Chapter 16b. Additionally, by the end of 2020, CMS will convene a technical advisory panel to periodically update the list of chronic conditions for MA plans to use when determining if an enrollee is chronically ill for purposes of section 1852(a)(3)(D)(iii) and for establishing eligibility for Chronic Condition Special Needs Plans (C-SNPs). For CY 2020, CMS will consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. MA plans do not have to submit as part of their bids or for CMS prior approval the processes by which they identify chronically ill individuals that meet the three pronged definition of chronically ill enrollee. However, all three criteria must be met for an enrollee to be eligible for the SSBCI authorized under section 1852(a)(3)(D) beginning CY 2020. MA plans should document their determinations that an enrollee is eligible for SSBCI based on the statutory definition noted above.

In addition to limiting the class of enrollees who may be eligible to receive the new SSBCI benefits, section 1852(a)(3)(D) requires that the specific SSBCI item or service have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic condition or illness.

In general, MA organizations have broad discretion in developing the items and services they may offer as SSBCI provided that the items or services have a *reasonable* expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic condition or illness. Some commenters expressed concern that the requirement that a SSBCI benefit have a reasonable expectation of improving or maintaining the health or overall function of the enrollee could exclude individuals with degenerative diseases from receiving these benefits because some medical conditions may worsen even with appropriate interventions and thus are not be able to be maintained or improved upon. However, CMS does not believe these individuals would necessarily be excluded for this reason. MA plans are not prohibited from offering an item or service that can be expected to improve or maintain the health or overall function of an enrollee only while the enrollee is using it. In other words, the statute does not require that the maintenance or improvement expected from an SSBCI result in a permanent change in an enrollee’s condition. Items and services may include, but are not limited to: meals furnished to the enrollee beyond a limited basis, transportation for non-medical needs, pest

control, indoor air quality equipment and services, and benefits to address social needs, so long as such items and services have a reasonable expectation of improving or maintaining the health or overall function of an individual as it relates to their chronic condition or illness.

In the draft Call Letter, we signaled that SSBCI items and services may not include capital or structural improvements to the home of the enrollee that could potentially increase property value. However, after reviewing comments, we do not believe such a limit is necessary to implement the statute and permit MA plans to offer SSBCI. Therefore, beginning CY 2020, MA organizations may offer items and services that include capital or structural improvements (e.g., permanent ramps, and widening hallways or doorways) if those items and services have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic condition or illness. While CMS does not provide any guidance or interpretation of other law that may apply to the provision of items and services as MA supplemental benefits under the MA program, we encourage MA organizations to take necessary steps to ensure compliance with all applicable laws.

MA coordinated care plans are required to "coordinate MA benefits with community and social services generally available in the area served by the MA plan" (§422.112(b)(3)). MA coordinated care plans may not classify such coordination or characterize otherwise available community services and resources as plan benefits if such services are not furnished or covered by the plan. MA plans are reminded that the plan must incur a non-zero direct medical cost for supplemental benefits; in the case of SSBCI, such incurred cost should be a non-administrative cost for providing the benefit even if it is not necessarily a cost paid to a medical provider. MA plans may contract with community-based organizations such as those providing other home and community-based services (HCBS) to provide supplemental benefits , including SSBCI, that are compliant with the statutory and regulatory requirements. For example, an MA plan could elect to offer, as a SSBCI, the provision of meals or food/produce and pay a community-based organization for furnishing the covered benefit. Community-based organizations can also help determine whether an individual meets the eligibility requirements for SSBCI. These organizations may already be providing services in the community and, in some cases, have contractual arrangements with Medicaid managed care or MA plans.

We note that some community services programs are funded by the HHS Administration for Community Living (ACL) and utilizing ACL programs would also be permissible in delivering these supplemental benefits. The Act also allows CMS to waive the uniformity requirements with respect to SSBCI, effective in CY 2020. As discussed in the CY 2019 Final Rule (83 FR 16440, 16481-82), the waiver authorized under section 1852(a)(3)(D)(ii) of the Act gives CMS the authority to allow MA plans to offer chronically ill enrollees supplemental benefits that are not uniform. Thus, beginning CY 2020, CMS will use this waiver authority to allow MA plans to vary, or target, SSBCI as they relate to the individual enrollee's specific medical condition and needs. In other words, SSBCI under this waiver may not be provided to a chronically ill enrollee

if that benefit does not have a reasonable likelihood of improving or maintaining that specific enrollee's health or overall function as it relates to the specific chronic condition or illness.

CMS solicited comments on whether we should permit consideration of other factors, like financial need, in determining permissible supplemental benefits for chronically ill enrollees. Overall, comments were supportive of using social determinants or social risk factors to establish benefit eligibility. However, we clarify here that the statute expressly limits these supplemental benefits to enrollees that are chronically ill. We have not identified authority to allow for other criteria or social risk factors to be used when determining eligibility for these benefits. Additionally, there must be a determination by the MA plan that the non-primarily health related benefit will have a reasonable expectation of improving the chronic disease or maintaining the health or overall function of the enrollee receiving the benefit. MA plans may make these beneficiary-specific determinations using internal criteria that are in accordance with the statute. We appreciate the comments on this matter and we will study the results of the VBID demonstration to inform future policy making on this topic.

We expect MA plans to develop objective criteria (e.g., health risk assessments) and maintain detailed documentation for determining when one chronically ill enrollee is eligible for a particular item or service and another is not. Note that maintaining detailed internal documentation is necessary to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS.

We remind plans that SSBCI are supplemental benefits and, therefore, must not be items or services covered by original Medicare. Non-primarily health related SSBCI offered under section 1853(a)(3)(D) may be proposed as supplemental benefits in a PBP. Plans are expected to briefly describe their benefits in the PBP in category B19 (CMS-HCC or ICD-10 codes must not be included in the note). The final determination of benefit status is made by CMS during the annual benefit package review.

We also remind MA plans that coverage requests from enrollees or providers, including requests for any supplemental benefits, should be treated similar to requests for other benefits furnished by an MA plan. If a request concerning coverage of a discrete item or service submitted to a plan fits within one of the actions defined as an organization determination under 42 C.F.R. § 422.566(b), then the coverage decision is subject to the Subpart M appeals process. Furthermore, MA plans are responsible for clearly identifying in the plan's Evidence of Coverage (EOC) what will and will not be covered. Any limitations on coverage should be clearly noted in the EOC, including the process and/or criteria for determining eligibility to receive a SSBCI under the new authority beginning CY 2020. We expect MA plans will establish reasonable safeguards to ensure enrollees are appropriately directed to care.

Provider Directories

The draft Call Letter emphasized that the accuracy of MAO provider directories continues to be a concern for the agency. Inaccurate provider directories may impede access to care and bring into question the adequacy and validity of the MAO's provider network.

As stated in the draft Call Letter, CMS recently concluded the third year of online provider directory reviews. We have reviewed the accuracy of at least one online provider directory from virtually every parent organization with a MA contract. Through the review process, we have gained tangible insight into directory accuracy, including what data elements are most likely to be inaccurate. We have shared individual results with each organization so they may correct their deficiencies. In addition, we have publicly posted a report on our CMS website each year. This report shared our review methodology, findings, and common drivers of deficiencies, as well as the individual plan results and corresponding compliance actions taken by CMS.

The data collected demonstrates there has been a lack of improvement in the accuracy of provider directories over the past three years. MA organization must improve the accuracy of their provider directories. CMS will continue its focus on provider directory accuracy at both the aggregate and individual plan-level. In addition, the agency looks to work with industry stakeholders to develop techniques and solutions towards this shared outcome to achieve more efficient and effective processes to produce accurate provider directories.

While CMS continues to stress the importance of accurate provider directories, we also recognize that achieving directory accuracy is a complex problem. As noted in the draft Call Letter, one common challenge shared by industry is that there is no centralized repository for provider directory data, often referred to as a "source of truth." As a consequence, the current process of verifying the accuracy of provider information can present an undue burden on providers, as multiple plans, in an effort to validate their directory information, ask providers the same validation questions. Many providers have contracts with multiple health plans. Therefore, without a single data source of provider data, multiple plans, in an effort to validate their own plan's directory, ask their contracted providers for the same information. This requires providers to separately and repeatedly provide this information to each plan with whom they contract.

CMS received a number of comments from a wide range of stakeholders representing plans, providers, and advocates. The majority of plans that commented were appreciative that CMS recognizes the complexities of achieving accurate provider directories. Advocates expressed support for CMS's focus on provider directory accuracy, yet expressed concern that the findings show that accuracy continues to be a problem. Providers submitting comments also expressed the need for CMS to continue to focus on provider directory accuracy.

Many plans commented that CMS should be lenient on those plans that have shown a good faith effort to improve provider directory accuracy. A number of plans expressed that CMS should not hold them accountable when they have made quarterly outreach to providers whose data is later

found to have errors. Similarly, a few plan commenters requested that plans not be held accountable for provider directory errors based on inaccurate information provided by the provider. Some plans also suggested that CMS establish a means of holding providers accountable for accurate directory data. Other plans suggested CMS conduct outreach to the provider community. Conversely, many provider and advocate commenters stated that CMS should continue to hold plans accountable through compliance or enforcement actions when provider directories are found to be non-compliant.

The majority of plan comments expressed support for an industry-wide solution. Many plans expressed that they want to work with CMS to develop a single source for directory data. Several plan commenters mentioned the National Plan and Provider Enumeration System (NPPES) as a potential starting point. Through the recently published proposed rule CMS-9115-P, (titled "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers", https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and) known as the Interoperability NPRM, CMS has proposed to require MA organizations, among other plan types, make provider directory data available through a standardized API. CMS agrees in large part with these commenters and is exploring options for assisting MA plans and providers in identifying a single source for demographic provider directory data. As we do so, we encourage a continued dialogue among all stakeholders to provide further focus to this important topic.

Physical Exam Supplemental Benefit for Special Needs Plans (SNPs)

Over the past several years, CMS has sought to improve care coordination and enhance the experience of care for beneficiaries, particularly those that are a part of the SNP population. We believe that specialized, targeted care through supplemental benefit offerings is one way to achieve this goal. Beginning CY 2020, SNPs may offer the Physical Exam supplemental benefit that is currently available to Non-SNP MA plans. As discussed in section 30.1 of the Medicare Managed Care Manual, a supplemental physical exam benefit would provide services beyond and distinct from those services required to be provided in the Annual Wellness Visit (a basic benefit because it is covered under Part B). Additionally, SNPs are still required to provide a higher level of care coordination and disease management as integral to the "special" care provided to their enrolled beneficiaries through the plan's development and CMS's approval of the SNP Model of Care (MOC) (42 C.F.R. § 422.152(g)). Therefore, the physical exam supplemental benefit would provide services beyond what is required as part of the SNP's regular care coordination and disease management responsibilities. To be considered an Annual Physical Exam that qualifies as a supplemental benefit by CMS, the exam must be provided by a qualified physician or qualified non-physician practitioner.

D-SNP Administrative Alignment Opportunities

In the draft Call Letter, we highlighted recent efforts to provide administrative flexibility that facilitates efforts by state Medicaid agencies and MA organizations to use Dual Eligible Special Needs Plans (D-SNPs) to integrate coverage of Medicare and Medicaid benefits.

For example, for those D-SNPs that provide both Medicare and Medicaid benefits to all their members— meaning D-SNPs with exclusively aligned Medicare and Medicaid enrollment—we have provided flexibility to integrate the description of Medicare and Medicaid benefits into the Summary of Benefits and other member materials. For D-SNPs whose membership is exclusively comprised of dually eligible individuals who are exempt from Medicare cost sharing—zero-dollar cost sharing D-SNPs—we have provided the opportunity for plan materials and the Medicare Plan Finder on Medicare.gov to reflect the $0 for all benefits covered by Medicare Parts A and B.

Through the Medicare-Medicaid Coordination Office, we provide state Medicaid agencies with technical assistance and information on plan performance and audit results of their contracted D-SNPs so that the quality of Medicare services delivered by those D-SNPs can inform state contracting strategies. We have also provided states the opportunity to ensure that state expectations for the delivery of managed long term services and supports and behavioral health services are integrated into the model of care employed by the D-SNPs that deliver those benefits.

We sought comment from stakeholders on these initiatives described above and on additional administrative alignment initiatives we could pursue either through rulemaking or through subregulatory guidance.

We received broad support from a range of stakeholders on these administrative alignment efforts and a diverse set of recommendations for new areas of focus, including aligning D-SNP supplemental benefits with Medicaid benefits and coordinating Medicare and Medicaid assessments. We thank the commenters for their input and will take it into consideration as we move forward with this effort.

D-SNP "Look-alikes"

In the draft Call Letter, we described the emergence of non-D-SNP MA plans (D-SNP look-alikes) that, because of benefit design and plan marketing strategy, enroll very high proportions of dually eligible individuals but avoid the requirements of being a D-SNP, citing the June 2018 report by the Medicare Payment Advisory Commission (MedPAC).[21] Numerous states, with support from CMS, are working to integrate Medicare and Medicaid benefits to improve the

[21] See June 2018 MedPAC Report to Congress at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.

experience of dually eligible individuals, enhance coordination of care, reduce institutionalization, and enhance opportunities for community living. We noted that D-SNP look-alikes may undermine these efforts, and we sought comment on the extent to which the proliferation of D-SNP look-alikes impacts informed consumer choice; competition and innovation; the provision of high-quality coordinated care that addresses the full spectrum of dually eligible individuals' care and service needs; state Medicaid policy and operations; financial incentives; provider burden; and development and sustainability of products for dually eligible individuals through which an enrollee can receive all Medicare and Medicaid services from one organization.

We received comments from a range of stakeholders, including states, beneficiary advocates, and MA organizations and Medicaid managed care organizations. State commenters were unanimous in their view that D-SNP look-alikes impede state efforts to integrate Medicare and Medicaid services through MMPs or D-SNPs and are confusing for beneficiaries. Comments from beneficiary advocates were critical of D-SNP look-alikes for failing to deliver the levels of integrated, coordinated care required of D-SNPs and MMPs and for undermining state and community efforts to improve the beneficiary experience in MMPs. Comments from MA organizations and Medicaid managed care organizations were split. Some MA organizations and Medicaid managed care organizations advocated that CMS take action to rein in the marketing of D-SNP look-alikes or require MA plans with high proportions of dually eligible enrollees to meet D-SNP requirements, including contracts with states. Other MA organizations commented that D-SNP look-alikes have a legitimate place in the MA marketplace in areas where there are no D-SNPs or MMPs and in locales where state integration efforts restrict contracting with D-SNPs to organizations that are also contracted to provide Medicaid benefits or limit D-SNP enrollment to full benefit dually eligible individuals enrolled in a companion Medicaid plan.

Overall, the comments reinforce that the proliferation of D-SNP look-alike plans impedes progress toward developing products that meaningfully integrate Medicare and Medicaid benefits for dually eligible individuals. D-SNP look-alikes allow MA organizations to circumvent enrollment restrictions and federal regulatory and state contracting requirements for D-SNPs and MMPs, undermining efforts to lower costs and improve the quality of care.

Commenters highlighted three principal areas that warrant further investigation and analysis and potential rulemaking:

- ***Benefit design and nondiscrimination:*** Commenters sought greater clarity on D-SNP look-alike benefit design and whether such benefit designs violated the prohibition at 42 C.F.R. § 422.100(f)(2) of benefit designs that are discriminatory or steer subsets of beneficiaries to specific plans. Certain MA organizations commented that benefit designs that preference supplemental benefits such as dental, vision, and over-the-counter benefits over reductions in cost sharing are appealing to dually eligible

individuals. MedPAC recommended rejection of applications from MA organizations to offer non-D-SNP MA plans that appear to be targeted at dually eligible individuals. We are considering these recommendations.

- ***Beneficiary education, marketing, and broker compensation:*** We received widespread encouragement to use a range of tools, including Medicare Plan Finder, State Health Insurance Assistance Programs, and CMS beneficiary communications to highlight the benefits of, and opportunity for enrollment in, integrated D-SNPs, MMPs, and PACE for dually eligible individuals. Commenters showed broad support for CMS efforts to ensure MA organizations do not market D-SNP look-alike plans as plans that coordinate Medicaid benefits, as particularly suited to dually eligible individuals, or as uniquely subject to rules that protect dually eligible individuals from cost sharing or for which Medicaid pays the full amount of plan cost sharing. Some commenters highlighted the role of differential agent and broker compensation between MMPs and D-SNPs as driving enrollment in D-SNP look-alikes and suggested outbound verification calls to ensure enrollment decisions for such plans are made with sufficient understanding by beneficiaries. We remain committed to ensuring all MA organizations abide by our marketing guidelines and that beneficiaries can make informed choices. We intend to consider these comments to inform future policy development.
- ***Enhanced requirements for MA plans with high proportions of dually eligible enrollees:*** A number of commenters, included MedPAC, recommended that CMS require MA plans with high proportions of dually eligible enrollees to meet D-SNP regulatory requirements, including the requirement to contract with the state. We intend to consider these comments to inform future policy development.

Parts A and B Cost-sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program

In the 2017 and 2019 Call Letters, CMS reminded plans of their obligations under 42 C.F.R. § 422.504(g)(1)(iii) to educate network providers about Qualified Medicare Beneficiary program (QMB) billing rules and to maintain procedures that ensure network providers do not discriminate against enrollees based on their payment status, e.g., QMB.

All MA providers, suppliers, and pharmacies must refrain from collecting Medicare cost-sharing for covered Parts A and B services from individuals enrolled in the QMB program (note: pharmacists may still collect Part D cost-sharing per 42 C.F.R. § 423.782). As a reminder, Programs of All-Inclusive Care for the Elderly (PACE) and Medicare-Medicaid Plans (MMPs)

in the capitated model of the Financial Alignment Initiative (FAI) do not charge coinsurance, copays, and deductibles for any Medicare Parts A or B services.[22]

To reinforce billing requirements, simplify compliance, and prevent improper billing, CMS has strongly encouraged organizations to affirmatively inform providers if member cost-sharing liability is zero dollars.

In June 2017, CMS informed plans about CMS sources of QMB information, including the Medicare Advantage Medicaid Status Data File, which provides the most current information about monthly dual status, including QMB status, and corresponding dual status codes.[23]

Prior to claims submission, MA plans can provide real-time information and indicators to providers through automated eligibility-verification systems, online provider portals, and phone query mechanisms; plans can also provide QMB status on member ID cards so that information is available when an individual presents the card at the pharmacy counter.

A new method exists for plans to notify pharmacies of a member's QMB status for Part B drugs claims at the point of sale. The National Council for Prescription Drug Plans (NCPDP) developed a new Benefit State Qualifier (BSQ) Value 51 to indicate to pharmacy providers that the individual is a QMB and cannot be liable for cost-sharing for Part B drugs.

The NCPDP description for BSQ value 51 is as follows:

Not paid under Part D, paid under Part C benefit (for MA-PD plan). Beneficiary is a Qualified Medicare Beneficiary - pharmacy should not attempt to collect cost-share, but instead should attempt to bill COB to Medicaid coverage.

CMS encourages MA-PDs to implement BSQ value 51 for additional protection for QMBs and to assist pharmacy providers in proper billing for this population.

Once claims are processed, plans can clearly indicate members owe $0 directly on the Explanation of Payment statements for providers. CMS has encouraged plans to incorporate QMB information in the Provider Remittance Advice (RA) based upon changes CMS reintroduced to the Medicare Fee for Service (FFS) RA on July 2, 2018.[24] CMS initially

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[22] Elimination of cost-sharing for enrollees of Medicare-Medicaid Plans may be found in the CMS Memorandum of Understanding with the state Medicaid agency for each demonstration, on the CMS website at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ApprovedDemonstrationsSignedMOUs.html; for PACE enrollees, it may be found in section 1894(b)(1)(A)(i) of the Act.

[23] See June 21, 2017 HPMS memo "Qualified Medicare Beneficiary Program Enrollee Status Resources."

[24] See updated Change Request 9911, discussed in the CMS MLN Matters Number MM10433, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10433.pdf

launched the FFS RA changes for QMB claims in 2017 but quickly suspended them to address formatting and other issues impacting states' ability to process QMB cost-sharing claims. CMS notified plans to rescind any RA changes based on the 2017 changes instead of the July 2018 changes to avoid the negative impacts on secondary claims processing.[25]

We received a number of comments supporting CMS's continued efforts to reduce inappropriate billing through broad-based education, enhancing existing systems for providers, and by encouraging plans to use various tools to inform providers of the QMB status of members. Commenters stated that, while recent CMS efforts have helped improve the situation for beneficiaries, billing problems persist and providers, in particular, need further education and assistance to identify the QMB status of enrollees.

One commenter recommended that CMS require plans to convey QMB information to providers. While we cannot impose new requirements through the Call Letter, CMS reminds MA plans of their obligations under 42 C.F.R. § 422.504(g)(1). CMS will continue to support plans in developing their own strategies to better inform providers of dual eligibility and QMB status, and explore additional steps to address and track billing problems to promote adherence to billing rules.

One commenter recommended that CMS consider modifying the wording of the response field on the BSQ 51 to make it easier for pharmacy providers to quickly process. CMS will pass along this recommendation to NCPDP, which maintains the claim response language.

Medicare Advantage Organizations Crossing Claims over to Medicaid Agencies

In the draft Call Letter, we requested comments on the ways to extend the benefits of the crossover process for services provided to dually eligible enrollees in Medicare Advantage plans. We noted that for most dually eligible individuals, Medicaid is responsible for Medicare deductibles and coinsurance for services under Parts A and B, within certain limits. This is true regardless of whether the individual is in Medicare FFS or an MA plan. Since 2001, CMS has automatically forwarded claims under Medicare FFS to state Medicaid agencies and other secondary payers to process for covering Medicare cost sharing. Under this automatic claims crossover process, providers do not need to submit separate claims to both Medicare and the state Medicaid agency, which greatly reduces provider burden.

A growing number of dually eligible individuals receive Medicaid benefits through Medicaid managed care plans, which may include the coverage of Medicare cost sharing. In 2016, we modified regulations at 42 C.F.R. § 438.3(t) to require that certain Medicaid managed care plans responsible for Medicare cost sharing enroll in Medicare's automated crossover process. In the November 14, 2018 Medicaid Managed Care Notice of Proposed Rulemaking (see 83 FR

[25] See April 3, 2018 HPMS memo "Qualified Medicare Beneficiary Program Information in Remittance Advice and Explanation of Benefits."

57264), we proposed to modify the requirement to permit other mechanisms of ensuring Medicaid managed care plans receive Medicare crossover claims. We believe the proposed changes would enhance state flexibility while continuing to reduce administrative burden on providers.

For providers serving dually eligible individuals in MA, however, there is no guarantee of an automated crossover process. This means the providers must directly bill Medicaid in addition to billing the MA plan. In areas in which a state Medicaid agency has delegated coverage of Medicare cost sharing to a Medicaid managed care plan, the provider has to take the extra step of identifying whether a state Medicaid agency or Medicaid managed care plan is responsible for covering the Medicare cost-sharing for dually eligible individuals, and then directly bill that state Medicaid agency or managed care plan.

We received several comments, all of which expressed support for CMS addressing this issue, and some of which provided specific suggestions. Commenters described challenges providers and MA plans face when coordinating cost-sharing for dually eligible individuals in an MA plan, including lack of access to real time Medicaid eligibility/enrollment data, different claims coding requirements between states and Medicare, and the multiplicity of entities involves. A number offered suggestions for moving forward, including establishing a centralized mechanism, standardizing claims processes and coding, and looking beyond crossover claims to more holistic sharing of eligibility and clinical information. Finally, we received some comments requesting CMS take into consideration the "lesser of" policy and its effect on providers serving people enrolled in the QMB program when considering next steps for coordinating MA plans' cost-sharing claims.

We appreciate the support for our efforts to address this issue and will consider comments and suggestions received as we move forward.

Interoperability and Prior Authorization Coordination

CMS is working with partners in the private sector to promote interoperability. In 2018, CMS began participating in the Da Vinci project, a private-sector initiative led by Health Level 7 (HL7), a standards development organization. For one of the use cases under this project – called "Coverage Requirements and Documentation Rules Discovery" – the Da Vinci project developed a Fast Healthcare Interoperability Resources (FHIR) standard that was balloted in September 2018 and performed ballot comment reconciliation between September 2018 and December 2018. In June 2018, in support of the Da Vinci project, the CMS Medicare FFS program began: (1) developing a prototype Documentation Requirement Lookup Service for the Medicare FFS program; (2) populating it with the list of items/services for which prior authorization is required by the Medicare FFS program; and (3) populating it with the documentation rules for oxygen and Continuous Positive Airway Pressure (CPAP) devices required by the Medicare FFS program. More information about the FFS Medicare program's

efforts to support these Da Vinci use cases can be found at: go.cms.gov/MedicareRequirementsLookup.

We encourage all payers, including but not limited to Medicare Advantage organizations and Part D plan sponsors, to follow CMS's example and align with the Da Vinci Project's Coverage Requirements and Documentation Rules Discovery work by: (1) developing a similar lookup service; (2) populating it with their list of items/services for which prior authorization is required; and (3) populating it with the documentation rules for, at least, oxygen and CPAP. By taking this step, MA organizations and Part D plan sponsors can join CMS in helping to build an ecosystem that will allow providers to connect their EHRs or practice management systems and efficient work flows with up-to-date information on which items and services require prior authorization and what the documentation requirements are for various items and services under that patient's current plan enrollment.

We received comments that were supportive of CMS's goal to promote interoperability and provide patients with electronic access to their health care information. Commenters explained that Part D plans would need access to Part A and B claims data to inform coverage determinations under Part D, which is currently not allowed. We acknowledge this limitation and encourage plans and sponsors to engage in these interoperability activities to the extent that it is currently possible.

Request for Information - Barriers for MA Plans or Providers in using Risk Based Arrangements for Pharmacy Benefits

CMS solicited comment on the potential use of risk based arrangements for pharmacy benefits in contracts between MA plans and contracted providers. We explained that risk-based arrangements in contracting for pharmacy benefits may be another tool to drive down the cost of Part B drugs in MA and Part D drugs for MA-PD plans. We requested information on the barriers, feasibility, and benefits/drawbacks for these types of arrangements between MA plans and contracted providers. We also noted that Part D rules prohibit a Part D sponsor from requiring a pharmacy to accept insurance risk as a condition of participation in its contracted pharmacy network. We note that our focus was to collect information about the potential for risk based arrangements between MA plans and non-pharmacy providers.

We appreciate and thank commenters for their input and will consider this information should we develop future policy or guidance on this topic.

Section III – Part D

Formulary Submissions

CY 2020 Formulary Submission Windows

The CY 2020 HPMS formulary submission window will open this year on May 13, 2019 and close at 11:59 p.m. PDT on June 3, 2019. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 3, 2019 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid and therefore a failure to submit and link a formulary to each plan that uses a formulary by the June 3 deadline will result in denial of that bid submission.

Following the review and approval of initial CY 2020 formulary submissions, a subsequent limited update window will be provided in August 2019. During this window, Part D sponsors may add drugs that are new to the Formulary Reference File (FRF), and may also make negative changes to existing formulary drugs, only if the affected drug is replaced by an equivalent generic or therapeutically similar drug (at the same or more enhanced formulary placement). We do not expect sponsors to make significant enhancements or significant negative changes to existing formulary drugs during this window, since the formulary version that was initially submitted to CMS for review was considered in the bid and Part D benefits review. There will also be an enhancement-only formulary window in September.

CY 2020 Formulary Reference File

CMS released the first CY 2020 FRF in March 2019. The March FRF release will be used in the production of the Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2019, in order to assist plan sponsors in satisfying meaningful difference and MA TBC requirements prior to bid submission. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

CMS will update the CY 2020 FRF prior to the June 3 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2013 and 2015, new Part D drugs cannot be included in the OOPC model since they would not have appeared in the survey. Further, given the limited timeframe between the May release of the CY 2020 FRF and the June 3 deadline, CMS is unable to accommodate an updated version of the 2020 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS advises plan sponsors that any newly added drugs on the May release of the CY 2020 FRF will not be included in the 2020 OOPC model.

Changes for CY 2020 Formulary Submission

For the CY 2020 plan year, CMS is implementing changes to the following formulary-related files:

Excluded Drug File

The Excluded Drug file is a supplemental file submitted by plans sponsors who provide coverage of Part D excluded drugs as part of their benefit offering. Only enhanced alternative plan designs have the ability to offer this type of benefit. Historically, the file format has been based on National Drug Codes (NDCs) submitted by Part D sponsors, which were then validated against an internal CMS excluded NDC file. NDCs that were submitted by sponsors but not contained within the CMS validation file were rejected, which necessitated a subsequent resubmission by the Part D sponsor. In an effort to reduce the burden on Part D sponsors to create and submit these files, and to streamline the CMS review of the Excluded Drug file submissions, CMS will provide plans with an Excluded Drug reference file for CY 2020. The Excluded Drug reference file will mirror the format of the current FRF. Providing the file of acceptable RXCUIs in advance to plan sponsors will enable them to better prepare their files, significantly reduce the size of the files, and simplify the submission and review process.

Improving Access to Opioid-Reversal Agents

Combating the opioid crisis is a top priority for the U.S. Department of Health and Human Services (HHS). The HHS Opioid Strategy includes targeting the availability and distribution of opioid-reversal agents as one of its five pillars. On April 5, 2018, the Surgeon General released an advisory statement[26] emphasizing the importance of the opioid-reversal agent naloxone, recommending that more individuals have access to this potentially lifesaving drug, as well as calling for expanded access to evidence-based treatment for opioid use disorder. According to the Centers for Disease Control and Prevention (CDC), the leading cause of injury death is unintentional opioid overdoses, accounting for 42,249 deaths in 2016 alone.[27] The rate of opioid overdoses in 2016 was a record high, and five times that seen in 1999.[28] It is a top priority for CMS to address the prescription opioid overdoses by ensuring appropriate access to potentially lifesaving interventions such as naloxone. When naloxone is administered timely, it can rapidly reverse most opioid overdoses. Naloxone can save lives by blocking the effects of opioids and quickly restoring normal breathing. Various naloxone formulations are on the market. Recently, there has been a call to increase access of naloxone through community-based distribution, state regulations, or other naloxone access laws. An estimated 45 states and the District of Columbia permit third-party prescriptions (i.e., prescriptions written to a third-party who is not at risk of overdose but who can administer naloxone to an at-risk individual).[29] Also, an estimated 49 states permit non-patient specific prescriptions through pharmacy standing orders, collaborative

[26] https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html
[27] See https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.
[28] See https://www.cdc.gov/drugoverdose/epidemic/index.html.
[29] See https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf.

practice agreements, or protocol orders to authorize pharmacists to dispense naloxone without a separate prescription written from the provider.[30]

Formulary and Benefit Designs

CMS is aware that high out-of-pocket costs could be a potential barrier to accessing opioid-reversal agents. In 2018, the top 10 PDPs and top 10 MA-PD plans by enrollment have placed naloxone prefilled syringes and nasal spray products primarily on Preferred Brand and/or Non-Preferred drug tiers, with average non-LIS beneficiary out-of-pocket costs of $31 and $42, respectively. In the draft CY 2020 Call Letter, we strongly encouraged Part D sponsors to, at a minimum, place naloxone products on their plan's generic tier(s) in order to improve access to opioid-reversal agents. We further encouraged the placement of these products on the Select Care Tier (i.e., a tier that provides for $0 or low cost-sharing) for those plans that utilize such a tier model. While the majority of commenters expressed support for improving access to opioid-reversal agents, they expressed concerns that inclusion of *all* forms of naloxone on generic tiers would inhibit a plans' ability to negotiate, potentially lead to an increase in naloxone list prices, may lead to higher premiums and could set a precedent that limits a Part D plans' ability to manage drug utilization. Taking all comments into consideration, in addition to the concerns over potential barriers to access of opioid-reversing agents, in this final Call Letter, we are encouraging sponsors to include at least one naloxone product on a generic or Select Care Tier. We will analyze and address any outliers that inappropriately restrict access to naloxone as part of our formulary review process. Providers should use clinical judgment to determine which dosage form would be most appropriate for their patients or their patients' caregivers.

Naloxone Co-Prescribing

Consistent with CDC Guideline recommendations[31] and HHS guidance[32], CMS encourages the co-prescribing of naloxone with opioid prescriptions to beneficiaries who are at an increased risk for opioid overdose. Studies have indicated that the co-prescribing of naloxone with prescription opioids has significantly lowered emergency department visits and decreased the number of opioid-related deaths by 50%.[33,34]

In an effort to improve access to naloxone where clinically appropriate, CMS encourages plan sponsors to ensure coverage for beneficiaries who are more susceptible to opioid-associated harm (e.g., substance use disorder, claims history of $\geq$ 50 morphine milligram equivalents per

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[30] See *id.*

[31] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

[32] See https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf.

[33] Coffin PO, Behar E, Rowe C, Santos GM, Coffa D, Bald M, and Vittinghoff E. Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain. Ann Intern Med. 2016; 165:245-252.

[34] Albert S, Brason FW, Sanford CS, Dasgupta N, Graham J, Lovette B. Project Lazarus: Community-Based Overdose Prevention in Rural North Carolina. Pain Medicine. 2011; 12:S77-S85.

day, concurrent benzodiazepine use). Part D sponsors could also consider more innovative approaches, such as patient-specific pharmacy messaging to alert pharmacists to provide naloxone to at risk beneficiaries taking opioids in states that allow for standing naloxone orders. CMS also recommends targeted education of prescribers and enrollees on co-prescribing of naloxone to prevent accidental overdoses and to sensitively address the needs of persons with opioid use disorders. While CMS understands that co-prescribing of naloxone cannot guarantee the prevention of opioid overdose deaths, it is an accessible intervention that can potentially reverse prescription and illicit opioid overdoses very quickly.

Because some patients may need naloxone to address opioid addiction for which they are not receiving legitimately prescribed medication, prescription of opioids at a certain morphine equivalent should not be the only factor considered by plans when determining the clinical appropriateness of naloxone prescribing.

Access to Medication-Assisted Treatment

While CMS continues to work closely with Part D sponsors and other stakeholders to help combat inappropriate opioid utilization, it is imperative to also ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). As initially noted in the CY 2017 Call Letter, CMS will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for MAT. Benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved. We continue to expect Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers. Commenters noted that therapies used for MAT in Part D can be diverted and/or abused, therefore, CMS recognizes that utilization management may be appropriate in some cases. As noted in previous Call Letter guidance, PA criteria that duplicates those requirements already set forth in the FDA Risk Evaluation and Mitigation Strategies and Drug Addiction Treatment Act of 2000 for applicable MAT products will not be approved. We also note that drug addiction, including an addiction to opioids, may be considered a disability under Federal civil rights laws and a covered entity is required to provide nondiscriminatory access to its health care programs, including evidence-based opioid use disorder treatment and recovery services, such as MAT where the law requires.[35]

Part D PBP MRx Enhancements

CMS recognizes that full closure of the coverage gap in CY 2020 may potentially impact how sponsors want to design their Part D benefit. CMS conducted a survey of plan sponsors in October 2018 to understand if the current PBP structure provides sufficient flexibility to describe intended benefits specifically related to the closure of the coverage gap. We would like to thank

[35] See the HHS Office for Civil Rights website for more information about nondiscrimination and opioid use disorder at https://www.hhs.gov/civil-rights/for-individuals/special-topics/opioids/index.html.

sponsors for the feedback we received, which may be used to inform and guide future PBP system changes (i.e., for CY 2021 or beyond). In the meantime, references to the coverage gap phase of the benefit will remain unchanged in the PBP, and in references noted below for the Part D Benefit Parameters section of the Call Letter.

Medication Therapy Management (MTM)

Annual Eligibility Threshold

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per 42 C.F.R. §423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries is specified as costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in 42 C.F.R. §423.104(d)(5)(iv). The 2019 MTM program annual cost threshold is $4,044. The 2020 MTM program annual cost threshold is updated using the annual percentage increase of 5.21% as specified in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2020 MTM program annual cost threshold is $4,255.

A couple of commenters urged CMS to lower the MTM program annual cost threshold because the high threshold is excluding many beneficiaries who may benefit from MTM services but do not meet the threshold (i.e., have lower drug costs due to use of generics). CMS will consider re-visiting the MTM program annual cost threshold and conduct analyses to explore options for lowering the threshold through rulemaking in the future.

As stated below under the heading "Improving Drug Utilization Review Controls", there is an opportunity for Part D sponsors to offer MTM services to beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking key potentiator drugs. Therefore, we continue to encourage plans to also offer MTM services to these beneficiaries who do not otherwise qualify for MTM.

Note, the SUPPORT for Patients and Communities Act requires at-risk beneficiaries under drug management programs to be eligible for Part D MTM programs beginning on or after January 1, 2021. We will consider feedback on MTM programs and drug management programs for future rulemaking.

Annually, Part D sponsors must submit an MTM program description to CMS through the Health Plan Management System (HPMS) for review and approval. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year. The Annual Calendar in this Call Letter highlights key dates for the submission of MTM programs and attestations, as applicable. Of note, the attestation deadline is two weeks after the deadline for submission of 2020 MTM programs in HPMS.

A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The 2020 MTM guidance memo will be released approximately one month before the 2020 MTM program submission deadline. The 2020 MTM guidance memo will include the MTM program submission template. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Comprehensive Medication Review Summary Standardized Format

Part D sponsors must offer each beneficiary enrolled in their MTM program a comprehensive medication review (CMR). An individualized, written summary in CMS's standardized format must be provided following each CMR. The current format, instructions, and frequently asked questions are posted on the CMS MTM web page at CMS.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html.)

The standardized format must be approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA). OMB has approved the current version of the MTM standardized format (CMS-10396; OMB control number: 0938-1154) until August 31, 2020. Based on the results of feedback from limited cognitive interviews with consumers and other stakeholders conducted in 2018, we will propose revisions to the standardized format with the intent of optimizing the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors. The revised format will be available for public comment in 2019 through the PRA process before submission to OMB for approval in 2020. An HPMS memo will be issued when the revised format is available for public comment.

Part D Benefit Parameters for Non-Defined Standard Plans

Part D sponsors have the ability to offer non-defined standard plans, under which they can modify certain benefit parameters, including tiered cost sharing. The CY 2020 Part D benefit parameters for Non-Defined Standard Plans are set forth in Table 23 below, addressing three key areas: PDP meaningful difference, tiered cost-sharing and Specialty Tier thresholds. Pursuant to 42 C.F.R. § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package (other than defined standard) or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area, as defined under § 423.265(b)(2), with respect to key characteristics such as cost-sharing, formulary structure, or benefits offered. As part of the final rule (CMS-4182-F) issued in April 2018, CMS eliminated the PDP enhanced alternative (EA) to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a service area. Pursuant to § 423.104(d)(2)(iii), tiered cost-sharing for non-

defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. Pursuant to § 423.578(a)(6)(iii), Part D sponsors may exempt a formulary tier in which it places very high cost Part D drugs and biological product items from its tiering exception process, known as the Specialty Tier. CMS provides the Specialty Tier threshold amount for the upcoming contract year annually in the Call Letter. Please refer to the Specialty Tiers section below for additional detail. Each of these benefit parameters are based on data from the previous contract year, and are therefore subject to change from year to year.

Benefit Review

As part of the Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Notice of Proposed Rulemaking (NPRM), which appeared in the November 28, 2017 issue of the Federal Register, CMS sought stakeholder input on how to best define the meaningful difference between basic and enhanced stand-alone prescription drug plans (PDPs). Although we received very few specific recommendations, we are mindful that a common request from stakeholders was for stability in the meaningful difference threshold. Therefore, we will maintain the minimum monthly cost-sharing out-of-pocket costs (OOPC) difference between basic and enhanced PDP offerings at the $22 threshold which was established for CY 2019. In other words, for CY2020, the expected OOPC of the basic plan should be at least $22 higher than the expected OOPC for the enhanced plan offering(s).

CMS makes all of the necessary tools and information available to sponsors in advance of the bid submission deadline, and therefore we expect all PDPs to submit bids that meet these standards. If CMS determines that a PDP sponsor is not meeting the CY 2020 meaningful difference standards following the submission deadline, the PDP will not be permitted to change its formulary (e.g., adding drugs) in a significant manner as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS-identified formulary review concerns negatively affects the formulary and bid review processes. For example, portions of the annual formulary review process are based on outlier analyses. If a Part D sponsor were to be permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely impacted. In addition, significant formulary changes will necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor’s formulary. To avoid meaningful difference issues, PDPs are strongly encouraged to make sure all Part D benefit and formulary changes are considered as part of their meaningful difference evaluation prior to submitting their final bids and formularies to CMS.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 23 have been met, we will continue to rely on the FDA application type to identify formulary drugs as applicable or non-applicable. The maximum coinsurance of 50% applies to tiers that contain only applicable drugs. If only non-applicable drugs or a combination of both non-applicable and applicable drugs are on a tier, then the maximum coinsurance of 15% applies. We remind

sponsors that when cost-sharing reductions beyond the standard benefit are offered through a supplemental Part D benefit, the plan liability is applied to applicable drugs for applicable beneficiaries before the manufacturer discount.

We will continue to scrutinize the expected cost-sharing amounts incurred by beneficiaries under coinsurance tiers in order to more consistently compare copay and coinsurance cost-sharing impacts. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty tiers that are greater than the standard benefit of 25%, we will compare the average expected cost-sharing amounts submitted by sponsors in the PBP to the established copay thresholds, as noted in Table 23 below, to determine whether the coinsurance values are discriminatory. Similarly, we will continue to evaluate the drug composition of copay tiers in order to assess whether the formulary and benefit structure is providing a meaningful benefit.

Specialty Tiers

Part D sponsors may exempt a formulary tier in which it places very high cost Part D drugs and biological product items from its tiering exceptions process, consistent with 42 C.F.R. §423.578(a)(6)(iii). In order for a Part D drug to be placed on this specialty tier, the sponsor-negotiated price must exceed a dollar-per-month threshold established by CMS. Similar to past years, we analyzed CY 2018 prescription drug event (PDE) data to identify the percentage of monthly fills that exceed the current specialty tier threshold of $670. We believe that a threshold that identifies outlier claims is appropriate, to ensure that only the highest cost drugs are eligible for placement on the specialty tier. Historically, around 99% of monthly PDEs have been below the specialty tier threshold; however, the current year's analysis indicated that this share has decreased, i.e., the percentage of 30 day-equivalent fills that exceeded $670 was 1.2%. For CY 2020, we intend to maintain the specialty tier threshold at $670 in an effort to balance plan flexibility with beneficiary access. We sought comment on the methodology that CMS should consider to evaluate specialty tier threshold changes. We appreciate the comments that we received, which were largely supportive of having a methodology in place to annually evaluate and adjust the specialty tier threshold, as appropriate. We will take these comments into consideration for the future.

Tier Composition

We expect Drug Tier Labels to be representative of the drugs that make up that tier. Sponsors will continue to have the option of selecting a Non-Preferred Brand tier or a Non-Preferred Drug tier, but not both. As such, the inclusion of a significant number of generic drugs on a tier that is labeled as brand is misleading and may lead to beneficiary confusion. CMS will continue to evaluate the brand/generic composition of the Non-Preferred Brand tier as part of the bid review process. Similar to CY 2019, we intend to maintain a maximum threshold of 25% generic composition for the Non-Preferred Brand tier for CY 2020. We would like to remind Part D

sponsors that they have the option to choose a tier model that incorporates a Non-Preferred Drug tier label if a larger proportion of generics will be included on that tier.

CMS will continue to afford Part D sponsors the flexibility to determine the cost-sharing structure that is most appropriate for their benefit design, including the ability to mix brand and generic drugs within the Non-Preferred Drug tier. To maintain transparency and meaningful benefit offerings for enrollees, we will continue to conduct outlier tests for those Part D sponsors who choose a copay structure for the Non-Preferred Drug tier. In order to demonstrate that the cost-sharing structure chosen provides a value for beneficiaries, and would not otherwise discourage enrollment by certain types of beneficiaries, we expect sponsors to evaluate and be prepared to provide written justification upon request. We expect the justification to include detailed information about the drugs on the Non-Preferred Drug tier, such as expected utilization, the formulary alternatives represented on more preferred tiers, and any tier placement strategy. Sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted. The majority of the comments received were in support of continuing to allow plans flexibility in their benefit design while maintaining the maximum threshold of 25% generic composition for the Non-Preferred Brand Tier for CY 2020.

Improving Access to Part D Vaccines

According to the Center for Disease Control and Prevention's (CDC) Surveillance of Vaccination Coverage Among Adults in the United States, National Health Interview Survey, 2016, vaccination rates remain low for tetanus and diphtheria (Td) and tetanus and diphtheria with acellular pertussis (Tdap) for adults age 65 and older, at 58% and 20% respectively.[36] While the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70% of adults for whom the vaccine is recommended remain unprotected.[37] In a 2010 Government Accountability Office (GAO) Survey of State Health Insurance Assistance Programs (SHIPs), 40% of SHIPs reported difficulty affording the cost-sharing as a barrier to beneficiaries accessing herpes zoster vaccine.[38] A 2018 study of Tdap and herpes zoster vaccine claims in Part D demonstrated that higher out-of-pocket cost-sharing was associated with higher rates of cancelled vaccination claims, suggesting vaccination was abandoned.[39] In this study, cost-sharing of $51 or greater was associated with a 2 to 2.7-times greater rate of cancelled

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[36] Hung, M-C., Williams, W.W., Lu, P-J., et al. (2018). Vaccination Coverage Among Adults in the United States, Center for Disease Control and Prevention. National Health Interview Survey, 2016. Available at: https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html.

[37] Office of Disease Prevention and Health Promotion. National Health Interview Survey, 2016. Available at: https://www.healthypeople.gov/2020/data-search/Search-the-Data#objid=4673.

[38] GAO-12-61 Medicare Part D Vaccinations. December 2011; https://www.gao.gov/assets/590/587009.pdf.

[39] Yan, S., DerSarkissian, M., Bhak, R.H., Lefebvre, P., Duh, M.S., & Krishnarajah, G. (2018) Relationship between patient copayments in Medicare Part D and vaccination claim status for herpes zoster and tetanus-diphtheria acellular pertussis, Current Medical Research and Opinion, 34:7, 1261-1269, DOI: 10.1080/03007995.2017.1416347.

vaccination claims compared with $0 cost-sharing. In an effort to improve access to Part D vaccines routinely recommended by the CDC for all adults, or based on age or certain health conditions, we continue to encourage Part D sponsors to either offer a $0 vaccine tier, or to place these vaccines on a formulary tier with low cost-sharing.

Improving Access to Generic and Biosimilar Medicines

The use of cost-effective therapeutic alternatives like generic and biosimilar medicines is critical to the current and long-term success of Medicare Part D. Robust price competition through generic and biosimilar medicines is important to ensuring patient access to therapy while constraining costs. Generic tiers provide meaningful out-of-pocket savings for seniors compared to the out-of-pocket costs for brands. The use of generic tiers benefits beneficiaries and taxpayers by encouraging the use of the lowest-cost preferred therapeutic option. Generic tiers lower out-of-pocket costs for beneficiaries and save the Medicare program money by offering an incentive to fill a lower-cost prescription. Therefore, CMS will continue to encourage Part D sponsors to prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products.

CMS sought comment regarding an alternative to the tier composition policy outlined above, whereby plan sponsors would be prohibited from placing generics on brand formulary tiers and brand drugs on generic formulary tiers, and eliminating the non-preferred drug tier. We also asked for comments regarding all possible impacts of adopting the proposed policy, including:

- Plan ability to meet the actuarial equivalence tests in the bid pricing tool.
- Anticipated impact on premiums and beneficiary cost sharing, including CMS-established cost-sharing thresholds and other tier requirements.
- Formulary drug coverage and other formulary benefit design impacts, including sponsors' negotiations with manufacturers.
- If it is appropriate to provide specific exceptions to the proposed policy for vaccines and naloxone agents or other categories or classes of drugs to be placed on lower cost-sharing tiers.
- Whether or not biosimilars should be treated the same as generic medications and if biosimilars and generic medications should be eligible for specialty tier placement if their cost exceeds the specialty tier threshold.
- The effect of a potential policy that FDA-approved, therapeutically equivalent generics be automatically included on a generic formulary tier immediately after launch.

We received numerous comments from Part D sponsors, trade groups, beneficiary advocates, and pharmaceutical manufacturers. A large number of plan sponsors commented with overwhelming

opposition to this alternative approach to tier composition citing reasons including increased out-of-pocket costs as a result of limited plan flexibility in formulary and benefit design, potential for increased generic and biosimilar prices, and the concern that the policy would lead to increased premiums. Most beneficiary advocacy groups were in support of an alternative policy under which plan sponsors would be prohibited from placing generics on brand formulary tiers and brand drugs on generic formulary tiers, and eliminating the non-preferred drug tier. Their reasons were largely based on claims made in one published analysis[40] that contended that tier placement has gotten worse for generics, which has caused an increase in out-of-pocket costs.

CMS analyses of formulary placement and PDE data comparing generic access in 2011 to 2019 do not indicate that this alternative approach would result in the beneficiary savings asserted in the cited report. CMS has concluded that a broad prohibition of the inclusion of generic drugs on non-preferred tiers would result in preferred formulary placement of a number of generic drugs that are high cost and/or high risk for adverse events, especially in elderly patients. This could increase out-of-pocket costs for generic medications in some circumstances. For example, in order to meet actuarial equivalence, plans may raise their generic tier copayment amount in order to account for the need to add more expensive generic drugs to the generic drug tier, increasing the cost for the majority of generic drugs on the formulary. This alternative tier composition policy could also result in an increase to Part D premiums due to reduction in flexibility in plan design and reduced negotiating leverage with drug manufacturers.

However, while CMS analysis of CY 2019 formularies shows robust access to cost-effective generic medications and that Part D sponsors have been achieving very high generic dispensing and substitution rates, we do note that there are limited instances when Part D sponsors are not including generic alternatives when available. Instead, sponsors are only covering the brand drugs, which decreases generic substitution and increases beneficiary costs. Further, we have noted that some sponsors, despite having the generic at a more preferred formulary status than the brand, are not achieving optimal generic substitution. While we are declining to change our tier composition policy at this time, CMS will continue to monitor beneficiary access to generic alternatives, utilization of multi-source brands when generics are available, and situations where the brand drug is situated more favorably in comparison to the generic with regards to tiering and utilization management. We will consider future policy changes should this trend continue.

For CY2020, we will finalize our existing tier composition policy outlined above, and will not prohibit plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tiers or eliminate the non-preferred drug tier. CMS will continue to review generic utilization and benefit designs with respect to generic formulary placement, including the tier

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[40] Avalere Health. “Generic Drugs in Medicare Part D. Trends in Tier Structure and Placement.” May 22, 2018. Available at: http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1526998792_Part_D_Generic_Tiering_White_Paper.pdf.

composition review and other benefit review outlier tests. CMS is appreciative of the comments we received and will consider them in the development of future policy.

Table 23: Benefit Parameters for CY 2020 Threshold Values

	CY 2020 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$22
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S[2,3]
Preferred Generic Tier	<$20[4]
Generic Tier	$20
Preferred Brand/Brand Tier	$47
Non-Preferred Drug Tier	$100
Non-Preferred Brand Tier	$100
Injectable Tier	$100
Select Care/Diabetic Tiers[5]	$11
Vaccine Tier	$0
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S[2,3]
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	33%
Select Care/Diabetic Tiers[5]	15%
Vaccine Tier	0%

	CY 2020 Threshold Values
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)	S[6]
Preferred Generic Tier	15%
Generic Tier	15%
Preferred Brand/Brand Tier	50%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	50%
Select Care/Diabetic Tiers[5]	50%
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$670

[1] The same Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold that was set for CY 2019 is proposed for CY 2020 (see above discussion under the Benefit Review section). The CY 2019 threshold was based on the 50th percentile of the November CY 2018 Bid Data run through the CY 2018 OOPC MPF model which incorporates CY 2018 Formulary Data, 2012/13 MCBS Data, and FDA application type for applicable/non-applicable determinations related to manufacturer discounts. For each parent organization, any cost-sharing OOPC comparison between a basic plan and EA plan in the same region must meet the minimum Enhanced Alternative Plan vs. Basic Plan threshold.

[2] These thresholds are based on the 95th percentile of the CY 2019 Bid Data. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary.

[3] "S" in the above chart refers to "standard retail cost-sharing" at a network pharmacy. Standard retail cost-sharing (S) is cost-sharing other than preferred retail cost-sharing offered at a network pharmacy.

[4] A separate maximum cost-share threshold for the Preferred Generic tier has not been established. Cost-sharing for the Preferred Generic tier need only be lower than that for the cost-sharing of the Generic tier. Equivalent cost-sharing for the Preferred Generic and Generic tiers will not be accepted, except in the case when a sponsor buys down the cost-sharing to $0 for both generic tiers.

[5] The Select Care Drug and Select Diabetic Drug Tiers must provide a meaningful benefit offering with low or $0 beneficiary cost-sharing for drugs targeting specific conditions (e.g., $0 tier for drugs related to diabetes and/or smoking cessation). We continue to expect cost-sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be $0.

[6] Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier

(partial tier coverage). If the additional gap cost-sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 15% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 70% manufacturer discount for applicable drugs.

PDP Crosswalk Policy and Solicitation of Comments

CMS is committed to promoting choice and flexibility in the Part D program while protecting beneficiaries' financial and health interests. Historically, this has included allowing stand-alone Part D plans (PDPs) that wish to terminate existing plan benefit packages (PBPs) at the end of a contract year to transfer, or crosswalk, enrollees to new plans in the following contract year under certain circumstances. CMS has also sought to minimize beneficiary disruption by restricting, under our statutory contracting authority, PDP sponsors' ability to reenter the PDP market for two years after they exit. While we did not propose changes to these policies for CY2020 in the draft Call Letter, we invited ideas regarding updating the circumstances under which CMS allows plan sponsors to crosswalk beneficiaries from one PBP to another and on the application of the two-year ban that we may take into consideration for future policy changes. We received responses from a number of stakeholders and we thank the commenters for their input. We continue to review the suggestions received in response to this solicitation to inform next steps as we evaluate this policy for future years.

Low Enrollment Plans (Stand-alone PDPs only)

CMS has the authority under 42 C.F.R. § 423.509(a)(4)(xiv) to terminate Part D plans (at the benefit package level) that do not have a sufficient number of enrollees to establish that they are viable plan options. CMS evaluates plan enrollment at the PDP region level. Plans are deemed low enrollment plans if the plan enrollment is below 1,000, and the plan is in the lowest quintile of enrollment within the specific PDP region. Prior to taking additional action on a low enrollment plan, CMS considers relevant factors such as: (1) whether the plan is a basic plan that is satisfying requirements set forth at 42 C.F.R. § 423.104(f)(2), and the organization's enhanced plan does not have low enrollment in the same region; (2) whether the plan has been in existence for three years or less; (3) whether the plan is offered nationally; (4) the total number of plan offerings in the applicable region; and (5) if the plan's premium currently falls at or below the low income benchmark premium amount. We will notify affected low enrollment plans that do not meet at least one of the five criteria above in the Spring of 2019. In these circumstances, the Part D sponsor will have the option to consolidate or non-renew the plan, or they may alternatively submit a strategic plan that describes how enrollment will be increased for the upcoming plan year. We intend to terminate a plan if it continues to be low enrollment for a second consecutive year despite a strategic plan aimed at increasing enrollment. In this instance, notice will be provided no later than August 1 for a termination effective December 31 of the same year, in accordance with 42 C.F.R. §423.509(a)(xiv). We will also notify Part D sponsors

that meet low enrollment criteria (< 1,000 members and within the lowest quintile for a given PDP region) but possess one of the five relevant factors for informational purposes only. No action will be required for those sponsors.

PDP Non-Renewal Policy Clarifications

PDP sponsors who non-renew their Part D contracts with CMS are subject to a prohibition, under section 1860D-12(b)(3)(B) of the Social Security Act, from re-entering a new stand-alone PDP contract for two years following the effective date of the non-renewal. This provision incorporates into Part D by reference the two-year ban that applies to MA organization-initiated contract non-renewals pursuant to section 1857(c)(4) of the Act. This authority is also codified into the Part D regulations at 42 C.F.R. § 423.507(a)(3), which state that CMS cannot enter into a new contract with the non-renewing organization in less than two years absent circumstances that warrant special consideration.

By preventing a sponsor's immediate re-entry into the PDP program following a contract non-renewal, the two-year ban promotes stability in the PDP market. In making a decision to non-renew, a sponsor must consider not just the market conditions for the immediately upcoming plan year, but also the potential cost of missing out on a second year of PDP business. The ban prevents sponsors from moving in and out of the stand-alone PDP program from year to year based on their own short-term analysis of the PDP market and their own financial and operational considerations without regard for the beneficiary disruption caused by a non-renewal. The rule places an incentive on sponsors to bid accurately and promotes the maintenance of a reasonably stable number of plans from which beneficiaries can make an election each year.

CMS believes the policy goals promoted by the two-year ban are applicable to a sponsor's non-renewal of its individual market plans in one or more PDP Regions but of less than its entire PDP sponsor contract. In effect, each PDP Region is its own micro version of the larger PDP market. PDP sponsors submit individual market plan bids on a per-PDP Region basis, and sponsors must offer enrollment in their plans to all eligible beneficiaries residing in that region. A sponsor exiting and re-entering a PDP Region on an annual basis would create an unstable set of plan choices for beneficiaries in that region, regardless of whether the sponsor continues to serve other PDP Regions. Also, a PDP sponsor contract is essentially the combination of several smaller contracts, each of which could stand on its own, governing the sponsor's Part D obligations for each PDP Region where the sponsor offers individual market PDPs and for which the sponsor has demonstrated that it meets requirements unique to that region, such as insurance licensure and pharmacy network adequacy. Accordingly, a sponsor's decision to discontinue offering individual market PDPs in a PDP Region is its own form of contract non-renewal, triggering the application of the two-year ban.

Since the start of the Part D program, CMS has informed sponsors that have advised us of their plans to non-renew individual market PDPs that a complete withdrawal from the individual PDP

market in any PDP Region would make that sponsor ineligible to return to that same PDP Region for two years, even if it continues its PDP sponsor contract in other PDP Regions. We are describing here our policy regarding application of the two-year ban to make certain that it is being applied consistently and that all sponsors can consider the impact of the policy when making decisions about withdrawing from the individual PDP market in a given PDP Region. In the draft Call Letter, we asked sponsors to comment on the impact of our two-year ban policy on their evaluation of whether to enter or exit the individual market in a PDP Region.

Finally, we emphasize that the two-year ban policy we describe here only applies to PDP Regions where a sponsor is discontinuing its participation in the individual market. The ban has no impact on a sponsor's eligibility to begin offering plans in another PDP Region, through a service area expansion, where it has not previously been offering individual market PDPs.

Improving Drug Utilization Review Controls in Medicare Part D

Medicare Part D Opioid Overutilization Policy

Opioid pain medications are effective at treating certain types of pain, and have serious risks such as increased tolerance, development of an opioid use disorder, and overdose. Addressing the nation's opioid epidemic is one of our top priorities, and we seek to employ bold, beneficiary-focused solutions.

CMS has been committed to a comprehensive strategy to combat this public health emergency with demonstrated success in the Part D program. Given the scope of the crisis, CMS published a roadmap in June 2018 to strengthen and broaden our efforts to address this issue. The roadmap details our three-pronged approach to combating the opioid epidemic going forward: 1) **prevention** of new cases of opioid use disorder (OUD); 2) expanding access to **treatment** for patients who have already developed OUD; and 3) using **data** from across the country to better target prevention and treatment activities.

The roadmap's approach is reflected in our 2019 Medicare Part D opioid overutilization initiatives. The new policies, which we proposed to continue for 2020, include drug management programs to better coordinate care when chronic high-risk opioid use is present, and improved safety alerts when opioid prescriptions are filled at the pharmacy:

- **Drug Management Programs**, codified in the CY 2019 Final Rule. https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

  As required by the Comprehensive Addiction and Recovery Act (CARA), in the CY 2019 Final Rule, CMS finalized the framework under which Part D plan sponsors may adopt drug management programs for beneficiaries who are at risk of misusing or abusing frequently abused drugs.

The rule codified many aspects of the retrospective Part D Opioid Drug Utilization Review (DUR) Policy and the Overutilization Monitoring System (OMS), with adjustments as needed to comply with CARA, by integrating them into the drug management program provisions. Under drug management programs, for the safety of the beneficiary, sponsors may limit at-risk beneficiaries' access to coverage of opioids and benzodiazepines to a selected prescriber(s) and/or network pharmacy(ies) (i.e., "lock-in"), and they may still implement beneficiary-specific claim edits for such drugs, as long as sponsors meet the regulatory requirements.

We also note that the SUPPORT for Patients and Communities Act, enacted on October 24, 2018, requires all Part D sponsors to have a drug management program (DMP) for plan years beginning on or after January 1, 2022.

- **Improved Opioid Safety Alerts, announced in the 2019 Medicare Parts C&D Final Call Letter. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.**

  In the 2019 Final Call Letter, CMS announced new strategies that took effect January 1, 2019 to enhance Medicare Part D sponsors' responsibilities to prevent and combat opioid overuse. We adopted a policy under which CMS expects Part D sponsors to implement a real-time opioid care coordination safety edit at 90 morphine milligram equivalent (MME), at the time of dispensing, as a proactive step to engage both patients and prescribers about overdose risk and prevention. This safety edit may include prescriber/pharmacy counts. We recommend including a threshold of 2 or more opioid prescribers in these edit specifications. For 2019, most Part D sponsors have included either a prescriber count, pharmacy count, or both in the specifications for this edit. Sponsors continue to have the flexibility to implement hard safety edits at a threshold of 200 MME or more, with or without prescriber/pharmacy counts. Additionally, to reduce the potential for chronic opioid use or misuse, all Part D sponsors should implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7-day supply.

CMS received some comments on the opioid safety edits, which were generally favorable towards continuing the current policies for 2020. A few commenters highlighted concerns about burden on healthcare providers, in particular the difficulties with communication between prescribers, pharmacists, and Part D sponsors in order to resolve rejected claims at point-of-sale. Other commenters were concerned with creating potential barriers to access for appropriate pain management, which could result in untreated pain. A few commenters asked us to clarify opioid safety edit exclusions and urged outreach and guidance to all stakeholders affected by policy changes. Other commenters suggested excluding additional patient populations.

CMS appreciates the comments from all stakeholders, which also reinforce the need for CMS and all stakeholders to continue to closely monitor implementation of the new policies and identify any unintended consequences. In the draft Call Letter, we reminded stakeholders that residents of long-term care facilities, beneficiaries in hospice care, those receiving palliative or end-of-life care, and beneficiaries being treated for active cancer-related pain should be excluded from the Medicare Part D opioid policies. These policies should not impact beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine.

Based on comments received and the resources cited below, in this final Call Letter, we are also recommending that beneficiaries with sickle cell disease be excluded from the opioid safety edits. The CDC Guideline for Prescribing Opioids for Chronic Pain stated that "given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease".[41] CMS recently released a report on the challenges of pain management for beneficiaries with sickle cell disease.[42] Sponsors are encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the opioid safety edits.

Part D sponsors should continue to focus their efforts on successful implementation of the policies referenced above. To support these efforts, CMS released comprehensive guidance for sponsors and educational materials for providers, beneficiaries, and other partners (pharmacies, professional organizations, advocacy groups, etc.), which are available on the Improving Drug Utilization Review Controls in Part D webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html. CMS will continue to update the FAQs to provide additional guidance as needed.

These documents include:

- Drug management program guidance memo, including beneficiary notices with instructions, and FAQs
- Updated Overutilization Monitoring System (OMS) and MARx technical guides
- Opioid safety edit FAQ memo
- Medicare Learning Network (MLN) Article: A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019
- Slide decks and tip sheets for prescribers, pharmacists, and patients, including a beneficiary fact sheet and letter sent by CMS to fee-for-service providers

[41] National Heart Lung and Blood Institute. Evidence-based management of sickle cell disease. Expert Panel report. Washington, DC: National Institutes of Health; 2014.

[42] https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data-highlights/Understanding-Pain-Management-in-Medicare-Beneficiaries-with-Sickle-Cell-Disease-.html.

In 2019 and 2020, CMS will gain experience with the new strategies and closely monitor the impact on Medicare Part D prescription opioid overuse to evaluate the need for potential modifications or development of alternative or additional approaches in the future. For example, since the beginning of 2019, CMS has monitored complaints data, appeals data, and other sources of information to identify any issues. While no systemic issues have been identified, CMS has identified educational opportunities and met with certain plan sponsors to address implementation concerns. The impact of our current policies on utilization to date is discussed later in this section.

Additional 2020 Call Letter Policies to Address the Opioid Epidemic

In addition to these policies aimed to reduce opioid overutilization in the Part D program, CMS is continuing to explore other initiatives to prevent new cases of opioid misuse, overdose, and death, and support beneficiaries who are already at-risk.

- CMS is implementing strategies to improve access to potentially lifesaving interventions and treatments, such as encouraging lower beneficiary cost-sharing (i.e., copays or coinsurance) for naloxone, as well as to promote co-prescribing of naloxone when clinically appropriate. See Improving Access to Opioid-Reversal Agents section, under Part D.
- CMS is reminding MA organizations that non-opioid pain management can be offered as a Part C supplemental benefit. CMS provided additional guidance with the goal of increasing the number of MA organizations who offer Part C supplemental benefits to address the opioid addiction epidemic. See Non-Opioid Pain Management Supplemental Benefits section, under Part C.
- CMS is implementing the revised PQA opioid overuse measures that better align with the CDC Guideline for Prescribing Opioids for Chronic Pain. Using these improved quality metrics, CMS will be able to better track trends in Medicare Part D opioid overuse, especially high-risk beneficiaries who use 90 MME or more. See Enhancements to the 2020 Part C & D Star Ratings and Future Measurement Concepts, under Parts C & D.

Future Changes to the Overutilization Monitoring System (OMS) Criteria

As noted above, we will gain experience with drug management programs in 2019. We have made significant system changes and enhancements to the OMS to implement these programs. In doing so, we revised and added OMS response codes to receive information from sponsors about their review and case management process. These response codes will be used by sponsors in 2019 and will enable CMS to perform more robust analyses to evaluate drug management programs, including how to better identify beneficiaries who are potentially at risk of misusing or abusing frequently abused drugs.

The OMS criteria for 2019, which we proposed to and will retain for 2020, are as follows:

Minimum OMS Criteria. All Part D sponsors with drug management programs must review beneficiaries who meet the minimum OMS criteria:

Use of opioids with an average daily MME greater than or equal to **90 mg** for any duration during the most recent 6 months and either: **3** or more opioid prescribers **and 3** or more opioid dispensing pharmacies, **OR 5** or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.

Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

Supplemental OMS Criteria. Part D sponsors with drug management programs may review beneficiaries who meet the supplemental OMS criteria as capacity allows:

Use of opioids (regardless of average daily MME) during the most recent 6 months with **7** or more opioid prescribers **OR 7** or more opioid dispensing pharmacies.

Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.

Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

In concert with our program analysis, in the draft Call Letter we sought feedback from Part D sponsors and other stakeholders on ways to expand and improve the OMS criteria to identify potential at-risk beneficiaries for 2021 and beyond.

The OMS criteria (i.e., clinical guidelines) must be developed in accordance with 42 C.F.R. §423.153(f)(16) and:

- Are developed with stakeholder consultation;
- Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of these factors;
- Are derived from expert opinion and an analysis of Medicare data; and
- Include a program size estimate.

We received several comments on this section of the draft Call Letter. Commenters were generally supportive of our proposal to retain existing OMS criteria for 2020 to allow sufficient time to analyze the impact of drug management programs on plan sponsors, beneficiaries, prescribers and others. Commenters felt that it is important to determine whether the increased

number of potential at-risk beneficiaries identified based on the expanded 2019 criteria are truly at risk for prescription drug abuse. Some commenters shared ideas about future changes to OMS criteria for drug management programs, including:

- Additional beneficiary exemption categories, such as sickle cell disease;
- More flexibility for plan sponsors in designing their drug management programs, such as provisions that would allow beneficiaries to be placed in the drug management program at the request of their prescriber(s) even if they do not meet OMS criteria;
- Additional drug classes to include in the definition of frequently abused drugs;
- Additional OMS flags, including potential non-adherence to MAT.

We thank commenters for their suggestions. While we did not propose any changes to the OMS criteria or exemption categories for drug management programs for 2020, we will consider these comments, perform additional data analysis, including program size estimates, for potential future changes to the OMS criteria or additional exemption categories. As noted above, we are recommending that beneficiaries with sickle cell disease be excluded from the opioid safety edits for CY 2020.

We also explored ways to improve identification of beneficiaries with active cancer-related pain and chain pharmacies with multiple locations that share real-time data. While commenters agree with the need to improve such identification, specific suggestions were limited. Likewise, comments were very supportive of improved identification of chain pharmacies with multiple locations that share real-time data, but were limited in concrete ideas to do so. Improvements like those suggested by commenters may require new or revised industry information databases. We remind stakeholders that CMS expects case management conducted by sponsors will identify necessary information to appropriately handle the case under the requirements applicable to DMPs. We thank commenters for their feedback and will continue to explore ways to improve identification of excluded beneficiaries and chain pharmacies with multiple locations that share real-time data.

Opioid Potentiator Drugs

Concurrent use of other central nervous system-active drugs with opioids, especially benzodiazepines, can increase an individual's risk of opioid overdose and death. We have identified and reported concurrent opioid and benzodiazepine use to Part D sponsors through the OMS since 2016.

Prior to 2016, the percent of opioid users, excluding beneficiaries with cancer or enrolled in hospice, who had at least one concurrent day of benzodiazepine use was about 24% (Table 24). From 2015 to 2017, the rate has decreased by almost 10%. There was also a decrease in concurrent long-acting opioid use from a high in 2013 of 2.9% of opioid users to the low of 1.6% in 2017. Our expectation is that Part D sponsors' initiatives will further decrease inappropriate

concurrent use. As finalized in the 2019 Call Letter, we expect sponsors to implement soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

On the other hand, the concurrent use of two other opioid potentiators[43] is on the rise. As we discussed in the 2019 Call Letter, gabapentin was identified as an independent risk factor for opioid-related deaths and is reportedly misused due to the euphoria associated with high dose use.[44,45] CMS remains concerned about the increase in gabapentin and pregabalin use among opioid users. As the focus on inappropriate prescription opioid use and misuse is intensifying, clinicians and patients may be looking for alternatives for their pain treatment.[46]

Table 24: Opioid – Potentiator Drug Concurrent Use and Duplicative Use Trends, 2012-2017	Concurrent Benzodiazepine Use	Concurrent Long-Acting Opioids*	Concurrent Gabapentin Use >=2400mg	Concurrent Pregabalin Use
	% Opioid** Users			
2012	N/A***	2.4%	3.9%	3.5%
2013	24.3%	2.9%	4.3%	3.7%
2014	24.3%	2.1%	4.7%	3.8%
2015	24.1%	2.0%	5.1%	3.9%
2016	23.3%	1.9%	5.6%	4.0%
2017	22.1%	1.6%	6.0%	4.1%

Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018

*Unique long-acting opioid is defined at the route, dosage form and strength.

** Opioids exclude powders, injectable, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, and opium tinctures.

***Part D coverage of benzodiazepines for all medically-accepted indications began January 1, 2013.

In the 2019 Call Letter, we announced the addition of information on the OMS reports to Part D sponsors on potential at-risk beneficiaries meeting the OMS criteria (based on opioid use) who are also receiving doses of gabapentin higher than 2400mg daily or pregabalin. We expect that when sponsors perform case management under the drug management program they consider the use of other drugs (e.g., benzodiazepines, gabapentin and pregabalin) in the review process.

We are continuing to work with the Office of the Inspector General (OIG) to identify potentiator drugs that may pose safety risks when combined with opioids. To date, seven states have added gabapentin to their Prescription Drug Monitoring Programs,[47] and some states are changing the

[43] A drug potentiator is defined as a chemical, herb, or other drug that is used to increase the effects of a substance and consequently, increasing both the substance's and the potentiator's abuse potential.

[44] Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. "Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case–control study." PLoS Med 14(10): e1002396.

[45] Evoy KE, Morrison MD, Saklad SR. Abuse and misuse of pregabalin and gabapentin. Drugs 2017;77:403-26.

[46] Goodman, CW, Brett, AS. "Gabapentin and Pregabalin for Pain — Is Increased Prescribing a Cause for Concern?" DOI: 10.1056/NEJMp1704633.

[47] http://www.nascsa.org/database/reports/stateProfiles.pdf

classification of gabapentin to a Schedule V drug.[48, 49] A study conducted in five areas of the United States showed that toxicology reports from 26% of opioid overdose deaths tested positive for gabapentin,[50] including 42% in Kentucky and 26% in North Carolina. In this study, gabapentin was less likely to be detected in decedents who tested positive for illicit drugs.

Furthermore, we believe it is important that Part D sponsors offer Medication Therapy Management (MTM) services to beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking potentiator drugs. We noted in the draft Call Letter that these beneficiaries may benefit from MTM services including a Comprehensive Medication Review, targeted medication reviews, and interventions with their prescribers.

Commenters generally supported the concurrent opioid-gabapentin/pregabalin flag, added in 2019 to OMS reports for potential at risk beneficiaries who received high dose gabapentin (>2400 mg). A few commenters expressed concern that residents of long term care facilities, those in hospice care, beneficiaries receiving end-of-life or palliative care, or beneficiaries being treated for active cancer-related pain are being flagged in OMS for concurrent use. As a reminder, these beneficiaries are excluded from the Medicare Part D opioid policies.

As noted above, some commenters suggested expanding the OMS to provide information on concurrent use of opioids and other potentiator drugs such as skeletal muscle relaxants, sedative hypnotics, and stimulants. CMS will perform additional analyses and evaluate potential enhancements to the OMS in the future.

We received several comments related to Part D sponsors offering MTM services to beneficiaries at risk of adverse events due to opioid overutilization or concurrent use of opioids and potentiator drugs. Commenters expressed concern about whether MTM is the best tool for managing these populations. We had not proposed to make any changes to MTM policies in the draft Call Letter, but will consider the comments received and conduct additional analyses to inform future rulemaking. Any potential MTM changes for 2021 and beyond would be implemented through rulemaking, as appropriate. See additional discussion related to MTM and the SUPPORT Act above under the heading “Medication Therapy Management (MTM)”.

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[48] https://www.michigan.gov/som/0,4669,7-192-29943_34759-466413--,00.html

[49] https://www.deadiversion.usdoj.gov/schedules/

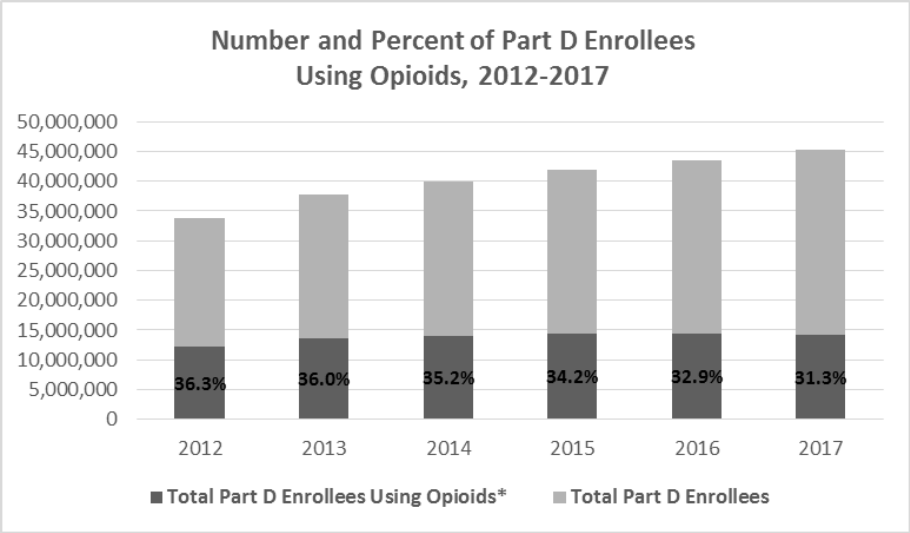
[50] Slavova, Svetla et al. “Prevalence of gabapentin in drug overdose postmortem toxicology testing results”. Drug Alcohol Dependence 2018 May 1;186:80-85

Impact of Medicare Part D Opioid Overutilization Policy

In 2013, CMS released a more robust Medicare Part D opioid overutilization policy. We have incrementally enhanced this policy over time and tracked its impact. We will also be in a position to track the objectives outlined in the President's Opioid Initiative[51] going forward.

The percent of Medicare Part D beneficiaries using opioids steadily decreased by 14% (36.3% to 31.3%) between 2010 and 2017, with the largest decrease (5%) from 2016 to 2017 (Figure 1). This is the result despite a 34% increase in Part D enrollment between 2012 and 2017. The absolute number of opioid users increased from 2012 to 2016, but in 2017 the trend was reversed and the number of users decreased by about 1.5% from 2016. Similarly, we observed a 13% decrease in opioid users from 2012 to 2017 after excluding beneficiaries with cancer or in hospice (data not shown).

Figure 1: Number and Percent of Medicare Part D Enrollees Using Opioids, 2012-2017



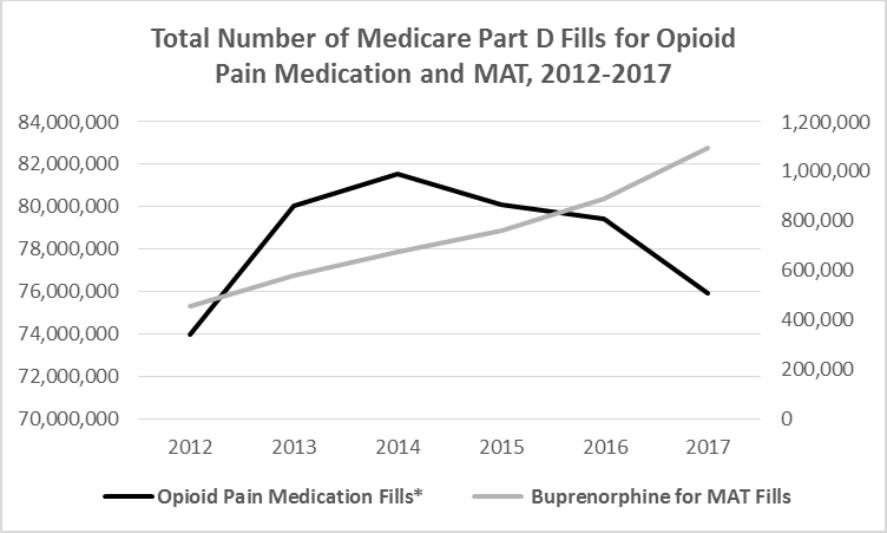
Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018.
*All Part D beneficiaries who received at least one opioid prescription, excluding powders, injectables, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, opium tinctures and buprenorphine for medication assisted treatment (MAT).

From 2012 to 2014, the number of prescription opioid pain medication fills increased (Figure 2), but decreased by 7% from 2014 to 2017 while overall Part D drug fills increased by 6% (data not shown). These results are a positive signal that opioid-related initiatives are reducing the opioid demand and supply in Medicare Part D.

[51] President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand. https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/

More significantly, there was a 141% increase in the number of buprenorphine for MAT fills from 2012 to 2017, a positive trend indicative of access to treatment of opioid use disorder treatment. The results were similar when excluding beneficiaries with cancer or in hospice (data not shown).

Figure 2: Number of Medicare Part D Fills for Prescription Opioid Pain Medication and Medication-Assisted Treatment (MAT), 2012-2017

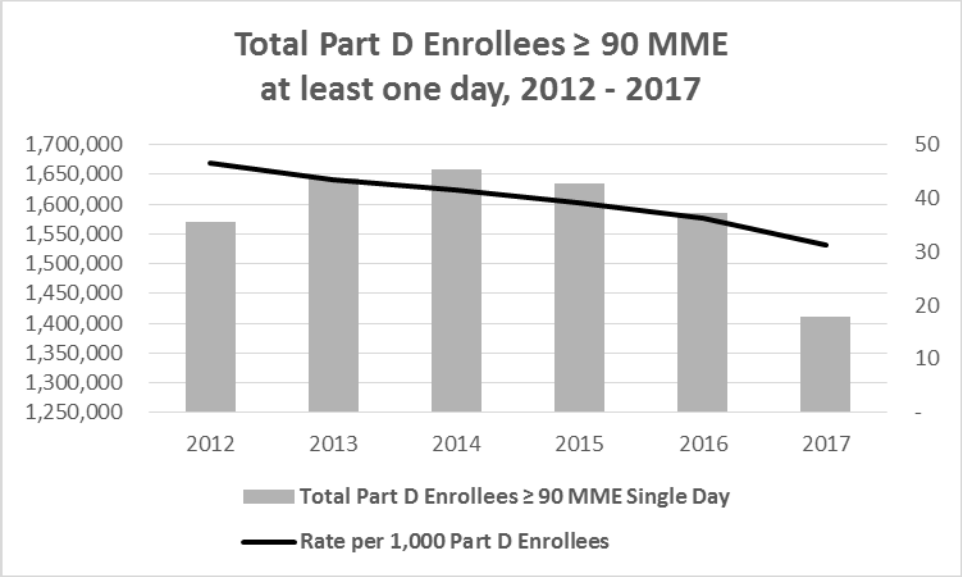


Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018;
*Opioid excludes powders, injectable, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, opium tinctures and buprenorphine for MAT.

Since 2013, we have encouraged Part D sponsors to use formulary-level controls at point of sale including safety edits. Some sponsors began to implement cumulative MME safety edits as early as 2015, and beginning in 2017, all sponsors were expected to implement soft and/or hard MME safety edits at point of sale. Prior to 2019, sponsors could set any soft opioid MME edit threshold at or above 90 mg per day and any hard MME edit at or above 200 mg per day.

We analyzed the number of Part D enrollees who met or exceeded 90 MME for at least one day with some exclusions (Figure 3). Overall, between 2012 and 2017, there was a 33% decrease in the share of Part D enrollees meeting or exceeding 90 MME for at least one day with the largest decrease (14%) in 2017 which coincided with CMS releasing more specific guidance for all Part D sponsors to implement MME edits and uptake of the CDC Guideline that was published the prior year. The absolute number of Part D enrollees receiving at least one day at 90 MME is at its lowest value in 2017. We expect to see continued progress with the implementation of the opioid care coordination safety edits at 90 MME in 2019.

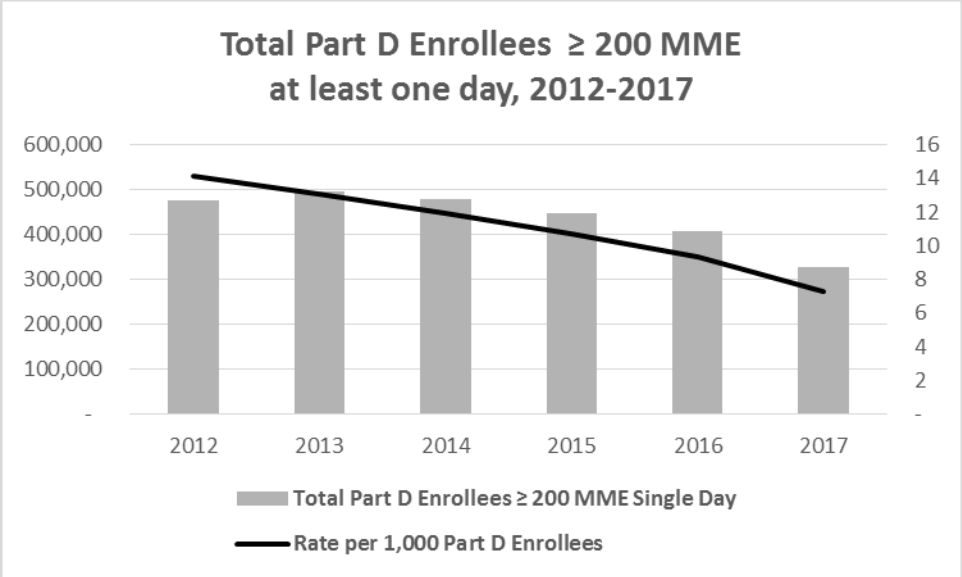
Figure 3: Total Number and Rate of Part D Enrollees who Met or Exceeded 90 Morphine Milligram Equivalents (MME) for at Least One Day, 2012-2017



Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018; Excludes beneficiaries with cancer, in hospice, or with overlapping dispensing dates for timely continued fills for the same opioid.

We also observed a larger 49% decrease in the number of Part D enrollees meeting or exceeding 200 MME for at least one day between 2012 and 2017 (Figure 4). Again, the greatest decrease (22%) was observed in 2017.

Figure 4: Total Number and Rate of Part D Enrollees who Met or Exceeded 200 Morphine Milligram Equivalents (MME) for at Least One Day, 2012-2017

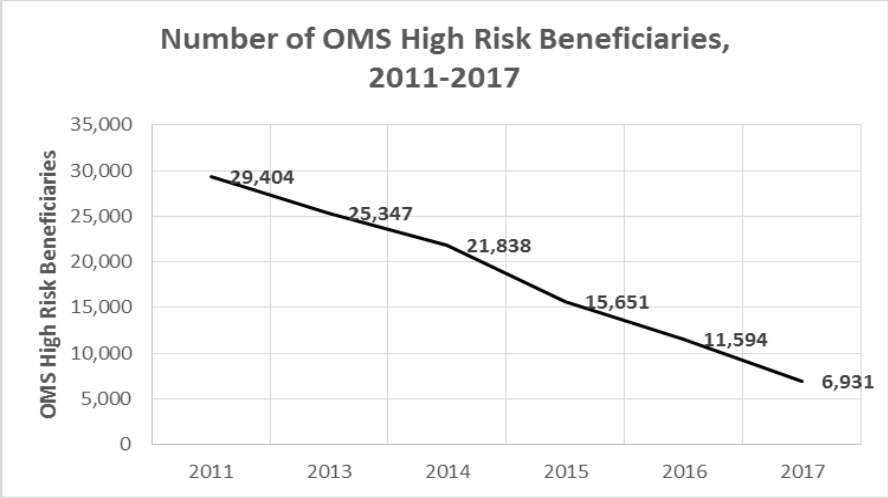


Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018; Excludes beneficiaries with cancer, in hospice, or with overlapping dispensing dates for timely continued fills for the same opioid.

The Part D enhanced retrospective opioid DUR policy and OMS began in 2013. The initial OMS criteria in place from 2013 to 2017 identified beneficiaries with at least 90 consecutive days with greater than 120 MME daily with more than three prescribers and more than three pharmacies contributing to their opioid claims, excluding beneficiaries with cancer or in hospice, during the previous 12 months.

In developing the OMS for 2013, we conducted pilots and testing in 2012. We use 2011 as the pre-pilot/pre-policy measurement period. As reported in the 2019 Call Letter, and presented in Figure E, the number of beneficiaries meeting the OMS criteria that was in place from 2013 to 2017 decreased by 76%. The greatest decrease (40%) was observed from 2016 to 2017.

Figure 5: OMS Part D Potential Opioid Overutilization Rates, 2011 – 2017



Source: Table 27 in 2019 Call Letter; 2011 = pre-policy/pilots; 2013 – 2017 OMS criteria: During previous 12 months, > 120 MME for at least 90 consecutive days with more than 3 opioid prescribers and more than 3 opioid dispensing pharmacies contributing to their opioid claims, excluding beneficiaries with cancer and in hospice.

In 2018, we updated the OMS criteria to incorporate best practices and the CDC Guideline, and 5,903 beneficiaries met the criteria. As already discussed, the OMS criteria was expanded again in 2019 with the implementation of the drug management programs.

Since January 2016, the OMS reports to Part D sponsors have included an Opioid Daily Dose metric for informational purposes:

- 120 MME Opioid Daily Dose rate: (# opioid days > 120 MME)/(1000 Opioid utilization days during the last 12 months).

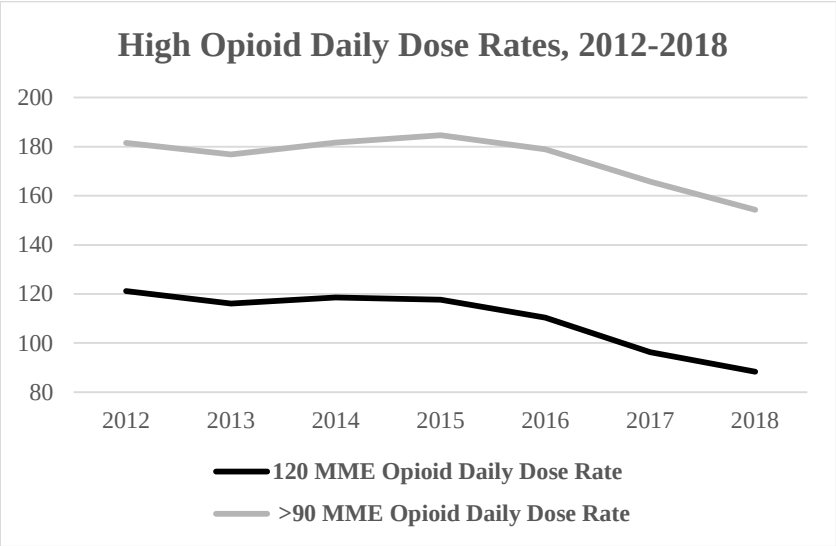
In 2018, CMS also began to report an additional Opioid Daily Dose metric with a 90 MME threshold and a 6-month measurement period.

- 90 MME Opioid Daily Dose rate: (# opioid days ≥ 90 MME)/(1000 Opioid utilization days during the last 6 months).

Furthermore, the 120 MME Opioid Daily Dose rate was revised to use a 6-month measurement period in 2018 and discontinued in the 2019 OMS reports as announced in the 2019 Call Letter. While we began to report these rates to Part D sponsors only more recently, we have tracked these rates since before the policy began. The rates have decreased significantly (Figure 6).

From 2012 to 2018, the annual rate of daily opioid use exceeding 120 MME per 1,000 opioid days decreased from 121.2 to 88.3 days, a 27% decrease. During the same period, the 90 MME per 1,000 opioid days rate peaked in 2015 (184.7 days) and then steadily decreased to 154.3 days, a 17% decrease. The largest decrease was observed from 2016 to 2017 (7%) following the release of the CDC Guideline, along with a similar decrease from 2017 to 2018 (7%) concurrent with the implementation of the revised OMS criteria, reporting of the 90 MME Opioid Daily Dose rate to sponsors, and the MME opioid safety edits.

Figure 6: Opioid Daily Dose Rates for 90 MME or More or Greater than 120 MME per 1,000 Opioid Use Days, 2012-2018



Source: 2012 –2016 Standard Analytic File; 2017 and 2018 Prescription Drug Event data as of 7/2/2018 and 01/02/2019 respectively; Excludes beneficiaries with cancer or enrolled in hospice.
*Opioids excludes powders, injectable, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, opium tinctures and buprenorphine-containing medications.

CMS also uses quality measures developed by the PQA to track overall trends in opioid overuse across the Medicare Part D program. In 2016, we began to report three PQA-endorsed opioid overuse measures through the Patient Safety reports.

The current measures are:

- Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 MME for 90 consecutive days or longer.
- Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
- Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 MME for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

A lower rate represents better performance for all measures.

Table 25 provides the statistics for each of the three opioid overuse measures by contract type for 2016 and 2017. Two-tailed T-tests were performed to compare rates. Overall the mean, median, and maximum values from 2016 to 2017 decreased for all three quality measures within both MA-PDs and PDP contracts. The distributions were statistically different for the OMP and OHDMP measures.

Table 25: Opioid Overuse Quality Measure Rates by Medicare Part D Contract Type, 2016 and 2017*

Measure	Type	Year	N	Mean	Std. Dev	MIN	Median	MAX	P-value
OHD	MA-PD	2016	668	31.6	23.9	0.0	29.2	203.4	0.15
		2017	645	29.5	26.9	0.0	27.2	333.3	
	PDP	2016	67	41.8	26.9	0.0	37.9	169.3	0.43
		2017	60	38.1	25.6	0.0	33.1	161.1	
OMP	MA-PD	2016	668	14.4	16.1	0.0	10.6	106.4	0.00
		2017	645	10.1	11.9	0.0	7.4	96.5	
	PDP	2016	67	11.8	8.0	0.0	9.9	36.0	0.00
		2017	60	8.3	6.1	0.0	6.6	23.2	
OHDMP	MA-PD	2016	668	1.0	1.8	0.0	0.3	17.6	0.00
		2017	645	0.5	1.2	0.0	0.0	16.8	
	PDP	2016	67	1.0	1.1	0.0	0.7	4.8	0.00
		2017	60	0.5	0.6	0.0	0.4	2.4	

Source: 2016 Prescription Drug Event data as of July 31 2017 and as of June 29 2018. Excludes beneficiaries with cancer or enrolled in hospice.
*In 2017, the data sources for identifying cancer diagnoses expanded to include both Part A & B claims and RAPS RxHCC for all contracts.

As discussed in the Enhancements to the 2020 Part C & D Star Ratings and Future Measurement Concepts section, we look forward to implementing the revised PQA metrics to better track CDC Guideline recommendations through industry endorsed performance measures.

While some progress has been made, more must be done. We will continue to work with all stakeholders to help address this devastating epidemic. The commitment shown by Part D sponsors, providers, and our federal partners has been tremendous. Together, we can improve patient safety while continuing to protect patients' access to medically necessary opioids.

Coordination of Benefits (COB) User Fee

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. The 2020 COB user fee will be collected at a monthly rate of $0.1166 for the first 9 months of the coverage year for a total user fee of $1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2020 bids.

In contract year 2020, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The Benefit Coordination and Recovery Center (BCRC) operation and maintenance;
- Drug data processing system management, which is used to collect prescription drug event (PDE) data for Part D payment purposes and to produce invoices for the coverage gap discount program;
- Medicare Advantage and Prescription Drug (MARx) system management of COB data;
- Additional Beneficiary Information Initiatives (ABII) system for COB data; and
- Review of Workers' Compensation settlement set-aside.

Part D Mail Order Auto-Ship Modifications

After soliciting feedback on possible modifications to the mail order auto-ship policy in the 2019 Call Letter, CMS proposed, starting in 2020, to permit Part D sponsors to offer voluntary opt-in auto-ship refills of established drug therapies.

In the 2014 Call Letter, we stated that for auto-ship prescriptions Part D sponsors should require their network retail and mail-order pharmacies to obtain enrollee consent to deliver a new or refill prescription prior to each delivery. The Call Letter guidance was an attempt to decrease the waste and unnecessary costs associated with unneeded or unwanted prescriptions that either 1) automatically shipped when newly ordered by the provider, or 2) automatically billed and shipped a refill after a certain number of days following the prior fill. We subsequently modified our policy to permit sponsors to allow network pharmacies to ship new prescriptions that were received directly from the provider for established mail order users without obtaining enrollee

consent prior to shipment (12/12/2013 HPMS memo: Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions).

Under our current policy, CMS expects sponsors to require their network pharmacies to obtain enrollee consent prior to shipping each refill. In the draft 2020 Call Letter, we proposed to permit sponsors to allow their pharmacies to replace this prior affirmative consent step with the option to provide no less than two shipping reminders prior to each shipment for enrollees that have been taking the drug for at least 4 consecutive months. We stated that such reminders would need to be sent well in advance of shipment (e.g., 25 and 10 days prior to shipping), providing sufficient time and information for a beneficiary to easily modify or cancel an order if needed.

We appreciate the comments submitted by stakeholders, who were largely supportive of the proposed change. Many commenters additionally recommended simplifications to the existing and proposed policies, many of which we agree could be adopted without affecting program goals. After considering the comments, we are finalizing the proposed changes to the policy with some refinements proposed by stakeholder comments to simplify the overall policy. Specifically, starting in 2020, CMS will permit Part D sponsors to allow their network pharmacies to offer a voluntary auto-ship program (i.e., no affirmative consent prior to shipping or delivering each new or refill prescription) if accompanied by the following enrollee protections:

- Pharmacy requires enrollees to opt-in to auto-ship refills on a drug-by-drug basis after an initial fill and permits enrollees to opt-out of auto-ship refills anytime;
- Pharmacy provides a minimum of 2 shipping reminders before each auto-shipped refill; and
- Pharmacy provides a refund for any unwanted fills. This applies to both new prescriptions ordered by the prescriber (consistent with the December 12, 2013 memo) and auto-shipped refills.

In order to simplify the proposal and reduce administrative burdens for enrollees, sponsors, pharmacies, and CMS, we are making the following modifications to the draft Call Letter proposal:

- Eliminating four month continuous therapy needed to qualify
- Eliminating separate annual consent (given drug-by-drug opt-in design)
- Permitting an approximate shipping date range (e.g., 2-3 days) in lieu of an exact date in shipping reminders
- Permitting information on how to determine cost-sharing of an upcoming shipment, in lieu of the exact cost sharing amount, and
- Clarifying pharmacies are permitted to request the enrollee return unwanted medications but the pharmacy cannot require return as a condition of the refund.

Use of mail order or any auto-ship arrangements within Part D cannot be mandatory. An auto-ship program needs to receive consent from the enrollee after an initial fill of a new drug to activate auto-ship for any subsequent refills of that drug. Consent to auto-ship a specific drug may not be assumed or activated at the same time as an initial fill, allowing time for the enrollee to initiate therapy and determine whether treatment with the new drug is tolerated and to be continued. An enrollee's voluntary selection of auto-ship for a specific drug implies a preference to have auto-shipped all refills authorized by the prescription order, unless or until they, their provider, or an authorized representative opts-out of that prescription (e.g., cancels auto-ship, cancels an order prior to shipping, or reports an order as unwanted after shipping). If a provider renews a prescription for an existing drug therapy, the auto-ship program may extend the previous enrollee consent to auto-ship the new prescription order and its authorized refills, unless instructed otherwise.

CMS is not recommending a specific method for how to provide the two shipping reminders. Such notification can be provided by phone, email, text, direct mailing, or other comparable means of communication (including in an alternative language if needed) and should be based on the enrollee's stated preferences. We expect all types of reminders to include all relevant information, including the name of the prescription drug, applicable cost sharing amount or information on how to determine the amount prior to shipping, scheduled shipping date or date range, and how to cancel the order. A missed call with no message left, bounce back email messages, or returned direct mailings would not count as successful shipping reminders and such members without reliable contact information would likely need to be evaluated for ongoing auto-ship interest or suitability.

We expect sponsors offering such programs to have a full refund policy whereby they require the pharmacy to return any cost-sharing paid by the enrollee (and delete the claim, and the sponsor deletes the PDE) for any auto-shipped refills that an enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned by the enrollee (or representative). Consistent with the December 12, 2013 memo, CMS also expects sponsors to require their pharmacies to provide refunds for unneeded or unwanted new prescriptions that are directly ordered by the prescriber and shipped without obtaining enrollee consent for the shipment. While a pharmacy may request return of the drug (such as through a pre-paid mailer), we expect sponsors to prohibit pharmacies from requiring return as a condition of the refund.

We expect sponsors to require their pharmacies to promptly discontinue automatic deliveries after information becomes available from CMS, the beneficiary, their provider or an authorized representative that the beneficiary entered a skilled nursing facility or elected hospice coverage. A drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug is available (or would be available but for the application of a deductible) under Part A or B for that individual as prescribed and dispensed or administered, such as during an inpatient hospital stay or home health episode.

CMS will continue to monitor the implementation of this policy through CTM tracking, data analysis, and other monitoring. CMS's evaluation of this policy will include consideration of enrollee experience, complaints, and on-going investigation into both adherence and waste directly attributable to auto-ship arrangements.

Finally, CMS recognizes that both our current policy and proposed changes to it did not adequately contemplate innovative dispensing models, such as those that synchronize medications, dispense for shorter timeframes than the traditional 90 days, etcetera. CMS believes the existing policy does not therefore prohibit such models. Further, the policy we are finalizing for CY 2020 sufficiently addresses such models and thus is applicable to them.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2020

Since 2013, CMS – in collaboration with our state partners – has implemented eleven capitated model demonstrations in ten states under the Medicare-Medicaid Financial Alignment Initiative. In some states, we will continue to build on the strong partnerships both CMS and the states have developed with participating Medicare-Medicaid Plans (MMPs) to provide high-quality, integrated care to individuals dually eligible for Medicare and Medicaid in CY 2020 and beyond.

Prior to each contract year, CMS provides information about the Medicare requirements and timeframes for renewal of MMP contracts. This section of the Call Letter reminds MMPs of those requirements and their timeframes. We will also provide guidance shortly after the issuance of the CY 2020 Final Call Letter about the applicability of the provisions in other sections of the Call Letter to MMPs.

As is the case for other Medicare Advantage (MA) and Part D plans, MMPs must submit a formulary, medication therapy management (MTM) program, and plan benefit package (PBP) each contract year, and annual submission timelines for MMPs are aligned with the standard MA and Part D schedule.

In addition to the requirements for MA and Part D plans, MMPs must also submit:

- On an annual basis, information to ensure the plan has a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid service providers, including long-term services and supports.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 26 below catalogues previously released guidance for MMPs or guidance that may be of particular interest to MMPs. CMS will release updated or new guidance as necessary; where

more recent guidance exists or is released for topics that appear in previously released documents, MMPs should use the most recent document.

Table 26: Previously Released MMP Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance and Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPEnrollment.html
State-specific Marketing Guidance and Model Materials	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.html
MMP Application and Annual Requirements	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPApplicationandAnnualRequirements.html
MMP Reporting Requirements	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPReportingRequirements.html
MMP Audit Programs	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPAuditPrograms.html
MMP Encounter Data Reporting	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPEncounterDataReporting.html
MMP Quality Withhold Methodology and Technical Notes	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPQualityWithholdMethodologyandTechnicalNotes.html
MMP Chronic Care Improvement Programs and Quality Improvement Projects	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPChronicCareImprovementProgramsandQualityImprovementProjects.html

Network Adequacy Determinations

The Medicare medical provider and facility portion of MMPs' network information will be due to CMS on the third Tuesday in September 2019 (i.e., September 18, 2019). This submission will ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. MMPs may assess the Medicare portion of their networks at any time using the organization initiated upload functionality in the HPMS Network Management Module (NMM). The current reference file, as referenced in the three-way contracts, that provides the MMP standards is available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPApplicationandAnnualRequirements.html as well as on the reference page within the NMM. CMS will release additional guidance on the submission process, including how MMPs will be able to submit exception requests, in the summer of 2019.

CMS appreciates the comment that we create a workgroup to assist states to define what constitutes network adequacy for LTSS and further develop non-mandatory guidance for states related to LTSS network standards; however, Medicaid service provider network standards are assessed based on state standards in accordance with the requirements set forth at 42 C.F.R. § 438.68.

Formulary and Supplemental Drug Files

Each contract year, MMPs must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. The required submissions for the integrated formulary are: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2020 Part D formulary guidance; and (2) an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs. Base formularies are due no later than June 3, 2019 at 11:59 p.m. PDT. Supplemental formulary files are due in HPMS on June 7, 2019 at 11:59 a.m. EDT.

MMPs must also submit an ADD file that includes non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. The ADD file may include drugs that have both Part D and non-Part D indications. Please note, however, that MMPs will not be permitted to submit these drugs for payment under the Part D program when prescribed for non-Part D indications. MMPs must ensure that they have measures in place to prevent inappropriate Part D claim submissions.

CMS will work with states to provide ADD file guidance to MMPs by May 2019. State guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC).

It is at the states' discretion whether to require MMPs to include one proxy NDC or multiple NDCs on the ADD file for each covered product.

Plan Benefit Package (PBP)

MMPs' plan benefit packages (PBPs) are reviewed annually to ensure that MMPs accurately describe the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits. CMS will launch the HPMS PBP module on April 5, 2019, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2020. In addition, CMS will release an online training module on the CY 2020 PBP software for plans on April 5, 2019.

MMPs must submit their integrated PBPs to CMS no later than June 3, 2019 (11:59 p.m. PDT). Non-timely submission of a PBP is considered a plan notice of non-renewal. In addition to the PBP, MMPs are required to submit the following as part of a complete bid submission:

- Service Area Verification
- Plan Crosswalk (NOTE: This is only for renewing contracts in CY 2020.)
- Formulary Crosswalk

CMS will work with states to issue PBP guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits by the time the PBP module is launched in April 2019. The PBP review is conducted jointly between CMS and states to ensure the data entry is consistent with minimum coverage and cost-sharing requirements under Medicaid, Medicare Parts A, B, and D, and each state's demonstration.

MMPs are provided some degree of flexibility with respect to PBP revisions after the time of final PBP approval. This flexibility is necessary to accommodate certain mid-year changes unique to MMPs, including but not limited to mid-year legislative changes to Medicaid benefits, as well as the timing of payment rate finalization.

CMS applies the following criteria to MMP requests to change or correct PBPs:

- PBP revisions to add or remove plan-offered supplemental benefits between the time of the release of the National Average Monthly Bid Amount in early August and sign-off of PBPs in HPMS in late August 2019 are permissible. This timeframe allows plans to accommodate any approved benefit changes in their required documents (including the Annual Notice of Change, Evidence of Coverage/Member Handbook, and Summary of Benefits) during the Annual Election Period.
- Rate-related PBP corrections are permissible during the Center for Medicare's annual correction window in September 2019 (see the calendar in this Call Letter for more information), but only for purposes of adding supplemental benefits to PBPs. MMPs that elect to correct their PBPs must work with their contract management team on an appropriate member communication strategy (e.g., issuance of corrected or revised

information for materials that have already been mailed to members; corrections or updates of hard copy and online versions of other materials for prospective members). We clarify that there will be no compliance penalty for a PBP correction provided an MMP meets these conditions.

- PBP corrections unrelated to rates and supplemental benefits that are requested during the Center for Medicare's annual correction window in September 2019 (see the calendar in this Call Letter for more information) will be considered changes due to plan error. As such, these PBP corrections (or any resultant corrections to MMPs' Annual Notice of Change and/or Evidence of Coverage/Member Handbook, which must be submitted in HPMS through the errata submission process in the Marketing Module) may be subject to compliance action, regardless of whether they are positive or negative changes.
- Any PBP corrections after the Center for Medicare's annual correction window in September 2019 will be considered on a case-by-case basis. In cases where a PBP correction is due to a mid-year legislative change to Medicaid benefits (or a benefit change made in a three-way contract amendment) and an MMP's previously approved PBP submission included a more generous supplemental benefit than the new Medicaid or demonstration benefit, the MMP will be required to continue to provide the more generous supplemental benefit for the remainder of the contract year. PBP corrections (or any resultant corrections to MMPs' Annual Notice of Change and/or Evidence of Coverage/Member Handbook, which must be submitted in HPMS through the errata submission process in the Marketing Module) due to plan error may be subject to compliance action, regardless of whether they are positive or negative changes.

Appendix 1: Methodology for Plan Finder (PF) Composite Price Accuracy Display Measure

CMS's drug pricing performance measure evaluates the accuracy of prices displayed on Medicare Plan Finder (PF) for beneficiaries' comparison of plan options. The accuracy score is calculated by comparing the PF price to the PDE price and determining the magnitude and frequency of differences found when the latter exceeds the former. This document summarizes the methods currently used to construct each contract's accuracy index. **Contract Selection**

This measure relies in part on the submission of pricing data to PF. Therefore, only contracts with at least one plan meeting all of the following criteria are included in the analysis:

Not a PACE plan
Not an employer plan
Part D plan
Plan not terminated during the contract year

Only contracts with at least 30 claims throughout the year are included in the accuracy measure. This ensures that the sample size of PDEs is large enough to produce a reliable accuracy score.

PF Composite Price Accuracy Score

To calculate the PF Composite Price Accuracy Score, the point-of-sale cost (ingredient costs plus dispensing fee) reported on each PDE claim is compared to the cost resulting from using the unit price reported on Plan Finder.[52] This comparison includes only PDEs for which a PF cost can be assigned. In particular, a PDE must meet seven conditions to be included in the analysis:

If the NPI in the Pharmacy Cost (PC) file represents a retail only pharmacy or retail and limited access drug only pharmacy, all corresponding PDEs will be eligible for the measure. However, if the NPI in the PC file represents a retail and other pharmacy type (such as Mail, Home Infusion or Long Term Care pharmacy), only the PDE where the pharmacy service type is identified as either Community/Retail or Managed Care Organization (MCO) will be eligible. NCPDP numbers are mapped to their corresponding NPI numbers. The corresponding reference NDC must appear under the relevant price ID for the pharmacy in the pricing file.[53]

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[52] Plan Finder unit costs are reported by plan, drug, days of supply, and pharmacy. The plan, drug, days of supply, and pharmacy from the PDE are used to assign the corresponding Plan Finder unit cost posted on medicare.gov on the date of the PDE.

[53] Plan Finder prices are reported at the reference NDC level. A reference NDC is a representative NDC of drugs with the same brand name, generic name, strength, and dosage form. To map NDCs on PDEs to a reference NDC, we use First Data Bank (FDB) and Medi-Span to create an expanded list of NDCs for each reference NDC,

The reference NDC must be on the plan's formulary.

Because the retail unit cost reported on Plan Finder is intended to apply to a 1, 2, or 3-month supply of a drug, only claims with a Days Supply of 28-34, 60-62, or 90-93 are included.[54] Claims reporting a different day supply value are excluded.

PDEs for dates of service during which the plan was suppressed from Plan Finder or where the relevant pharmacy or drug was not reported in Plan Finder are not included since no Plan Finder cost can be assigned.[55]

PDEs for compound drugs or non-covered drugs are not included.

The PDE must occur in Quarter 1 through 3 of the year. Quarter 4 PDEs are not included because PF prices are not updated during this last quarter.

The PF Composite Price Accuracy Measure factors in both how much and how often PDE prices exceeded the prices reflected on the PF. The contract's PF Composite Price Accuracy score is the average of the Price Accuracy Score, which measures the difference between PDE total cost and PF total cost,[56] and the Claim Percentage Score, which measures the share of claims where PDE prices are less than or equal to PF prices.

Once PF unit ingredient costs are assigned, the PF ingredient cost is calculated by multiplying the unit costs reported on PF by the quantity listed on the PDE. The PDE cost (TC) is the sum of the PDE ingredient cost paid and the PDE dispensing fee. Likewise, the PF TC is the sum of the PF ingredient cost and the PF dispensing fee that corresponds to the same pharmacy, plan, and days of supply as that observed in the PDE. Each claim is then given a score based on the difference between the PDE TC and the PF TC. If the PDE TC is lower than the PF TC, the claim receives a score equal to zero. In other words, contracts are not penalized when point-of-sale costs are lower than the advertised costs. However, if the PDE TC is higher than the PF TC,

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consisting of NDCs with the same brand name, generic name, strength, and dosage form as the reference NDC. This expanded NDC list allows us to map PDE NDCs to PF reference NDCs.

[54] If a plan's bid indicates a 1, 2, or 3 month retail days supply amount outside of the 28-34, 60-62, or 90-93 windows, then additional days supply values may be included in the accuracy measure for the plan. For example, a plan that submits a 3 month retail supply of 100 days in their bid will have claims with a days supply of 90-100 included in their accuracy measure calculation.

[55] Because sanctioned plans typically are not suppressed on MPF and display data to the plan's current enrollees only, non-suppressed sanctioned plans will have their data during the sanction counted towards the measure.

[56] PF total costs are rounded to the nearest cent. For example, if the PF total cost is $10.237, then it is rounded to $10.24. PF unit costs are not rounded.

then the claim receives a score equal to the difference between the PDE TC and the PF TC.[57,58] The contract level PF Price Accuracy Index is the sum of the claim level scores and PDE TC across all PDEs that meet the inclusion criteria, divided by the PDE TC for those same claims.

The PF Claim Percentage Index is the percent of all PDEs that meet the inclusion criteria with a PDE TC higher than the PF TC. Note that the best possible PF Price Accuracy Index is 1, and the best possible PF Claim Percentage Index is 0. This occurs when the PF TC is never lower than the PDE TC. The formulas below illustrates the calculation of the contract level PF Price Accuracy Index and PF Claim Percentage Index:

$$\text{Price Accuracy Index} = \left(\frac{\sum_i \max(TC_{iPDE} - TC_{iPF}, 0) + \sum_i TC_{iPDE}}{\sum_i TC_{iPDE}} \right)$$

where

TC_{iPDE} is the ingredient cost plus dispensing fee reported in PDE_i, and
TC_{iPF} is the ingredient cost plus dispensing fee calculated from PF data, based on the PDE_i reported NDC, days of supply, and pharmacy, then rounded to the nearest cent.

$$\text{Claim Percentage Index} = \left(\frac{\sum_i Claims_{iPDE>PF}}{\sum_i Claims_{iTotal}} \right)$$

where

$Claims_{iPDE>PF}$ is the total number of claims where the PDE price is greater than the rounded PF price

$Claims_{iTotal}$ is the total number of claims

We use the following formulas to convert the Claim Percentage Index and Price Accuracy Index into the PF Composite Price Accuracy score:

$$\text{Claim Percentage Score} = (1 - \text{Claim Percentage Index}) \times 100$$

$$\text{Price Accuracy Score} = 100 - [(\text{Price Accuracy Index} - 1) \times 100]$$

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[57] To account for potential rounding errors, this analysis requires that the PDE cost exceed the rounded PF cost by at least a cent ($0.01) in order to be counted towards the accuracy score. For example, if the PDE cost is $10.25 and the rounded PF cost is $10.24, the 1-cent difference would be counted towards plan's accuracy score. However, if the rounded PF cost is higher than $10.24, the difference would not be considered problematic, and it would not count towards the plan's accuracy score.

[58] The PF data includes floor pricing. For plan-pharmacy drugs with a floor price, if the PF price is lower than the floor price, the PDE price will be compared against the floor price.

$$\text{PF Composite Price Accuracy Score} = (0.5 \times \text{Claim Percentage Score}) + (0.5 \times \text{Price Accuracy Score})$$

The score is rounded to the nearest whole number.

Example of PF Composite Price Accuracy Score Calculation

Example of PF Table M-1 shows an example of the PF Composite Price Accuracy Score calculation. This contract has 4 claims, for 4 different NDCs and 4 different pharmacies. This is an abbreviated example for illustrative purposes only; in the actual accuracy index, a contract must have 30 claims to be evaluated. From each of the 4 claims, the PDE ingredient cost, dispensing fee, and quantity dispensed are obtained. Additionally, the plan ID, days of supply, date of service, and pharmacy number are collected from each PDE to identify the PF data that had been submitted by the contract and posted on Medicare.gov on the PDE dates of service. The NDC on the claim is first assigned the appropriate reference NDC, based on the brand name, generic name, strength and dosage form. Using the reference NDC, the following PF data are obtained: brand/generic dispensing fee (as assigned by the pharmacy cost file) and unit cost (as assigned by the Price File corresponding to that pharmacy and days of supply on the date of service). The PDE cost is the sum of the PDE ingredient cost and dispensing fee. The PF cost is computed as the quantity dispensed from the PDE multiplied by the PF unit cost plus the PF brand/generic dispensing fee (brand or generic status is assigned based on the NDC), and then rounded to the nearest cent. The last column shows the amount by which the PDE cost is higher than the rounded PF cost. When the PDE cost is less than the rounded PF cost, this value is zero. The Price Accuracy Index is the sum of the last column plus the sum of PDE costs divided by the sum of PDE cost. The Claim Percentage Index is the number of rows where the last column is greater than zero divided by the total number of rows.

Table M-1: Example of PF Composite Price Accuracy Score Calculation

NDC	Pharmacy Number	PDE Data					Plan Finder Data				Calculated Values			
		DOS	Ingredient Cost	Dispensing Fee	Quantity Dispensed	Days' Supply	Biweekly Posting Period	Unit Cost	Dispensing Fee		Brand or Generic Status	Total Cost		Amount that PDE > PF
									Brand	Generic		PDE	PF	
A	111	1/8/2016	3.82	2.00	60	60	1/4/16-1/17/16	0.014	2.25	2.75	B	5.82	3.09	2.73
B	222	1/24/2016	0.98	2.00	30	60	1/18/16-1/31/16	0.83	1.75	2.50	G	2.98	27.40	0
C	333	2/11/2016	10.48	1.50	24	28	2/1/16-2/14/16	0.483	2.50	2.50	B	11.98	14.09	0
D	444	2/21/2016	47.00	1.50	90	30	2/15/16-2/28/16	0.48	1.50	2.25	G	48.50	45.45	3.05
											Totals	69.28		5.78
											Price Accuracy Index			1.08343
											Claim Percentage Index			0.5
											PF Price Accuracy Score			71